

Trancatheter Retrieval of the Chronically Implanted Leadless Tines - based Pacemaker

Neužil P, Petrů J., Chovanec M., Šedivá L., Janotka M.,
Hála P., Chudiak B., Tousek M., Funasako M., Brada J.,
Mudroch M., Mráček M., Baroch J.

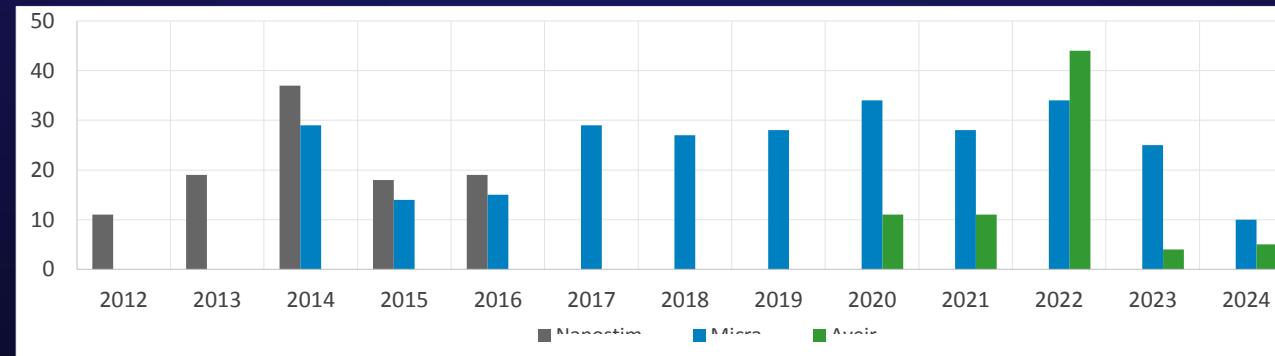
*Kardiocentrum Nemocnice Na Homolce
Praha*

1



Leadless stimulace v NNH

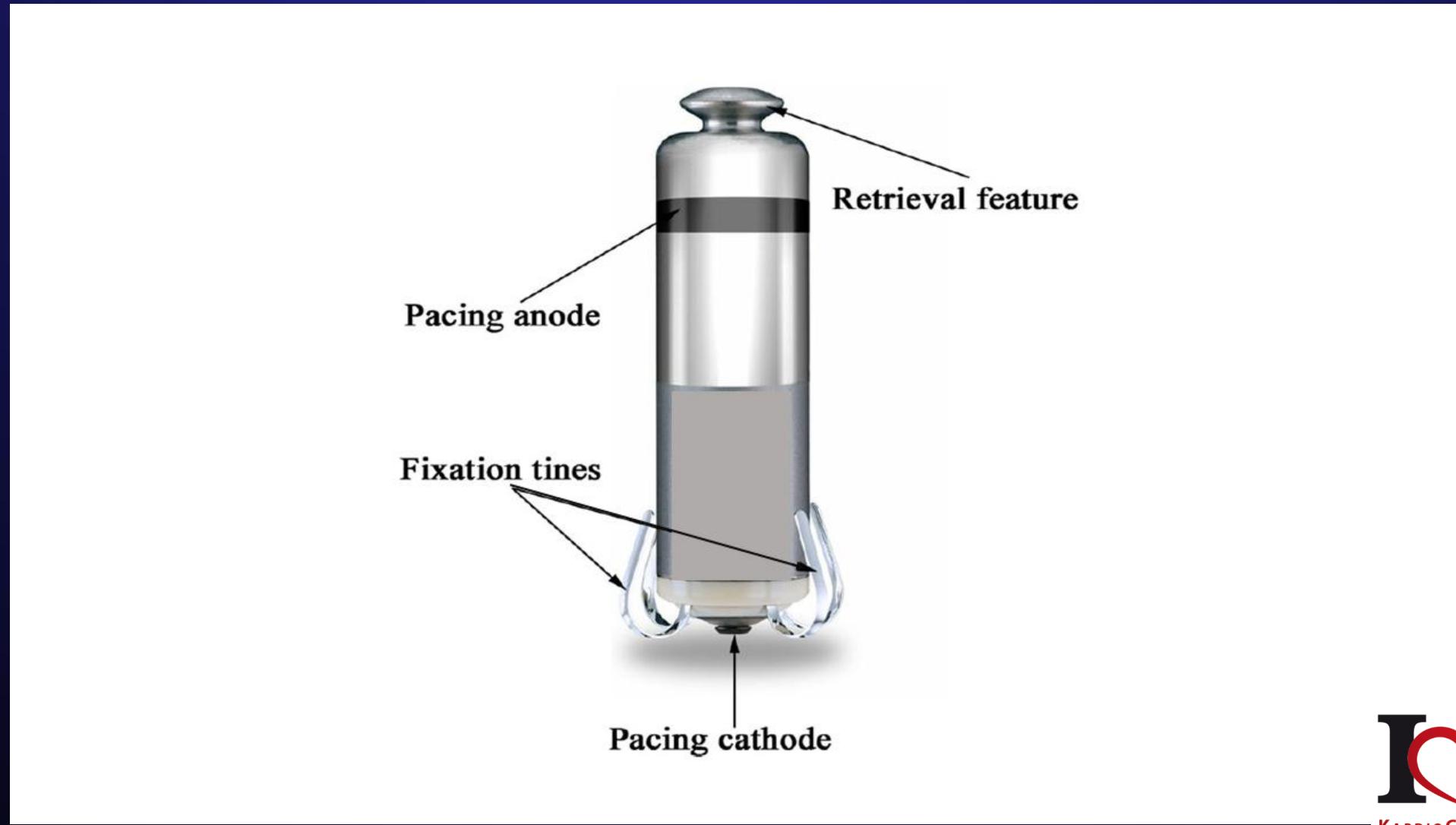
Leadless pacing v NNH: 2012 - 2024	
Σ	491 Nanostim 104, Micra TPS 273(VR 249, AV 24), Aveir 113 (VR 35, AR 2, DR 2x38), Modular ATP(Empower) 1
Věk	70,5 (20 – 92) let
Muži	311 (64%)
Úspěšnost	99%
Stimulační parametry	Stim.práh: < 1 V / 0,25- 0,4 ms Velikost vlny R: 4,6 – 20 mV
Jiná než VVI stim.	8x (2 x leadless + WiCS, 6 x leadless + S-ICD)
Komplikace	0,8 % (4x dislokace) 0,2 % revize třísla, infekce, 1x perforace



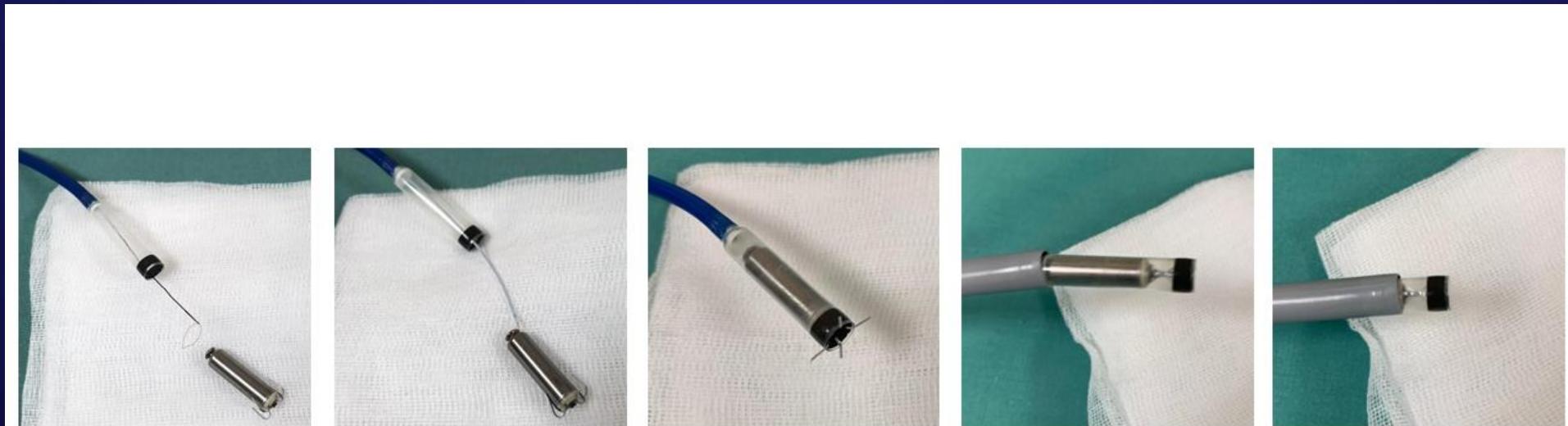
NNH: unikátní zkušenosti jednoho centra

	Leadless pacing v NNH: 2012 - 2023
Σ	448 Micra TPS 256, Micra AV 23, Nanostim 103, Aveir VR 28, Aveir DR 38
Věk	70,5 (20 – 90) let
Muži	235 (56,5%)
Úspěšnost	99%
Stimulační parametry	Stim.práh: < 1,5 V / 0,25ms Velikost vlny R: 8 – 20 mV
Jiná než VVI stim.	4x (2 x <u>leadless + WiCS</u>, 2 x <u>leadless + S-ICD</u>)
Komplikace	0,9% 4 dislokace 0,2% 1 srdeční tamponáda 0 % revize třísla, infekce, smrt

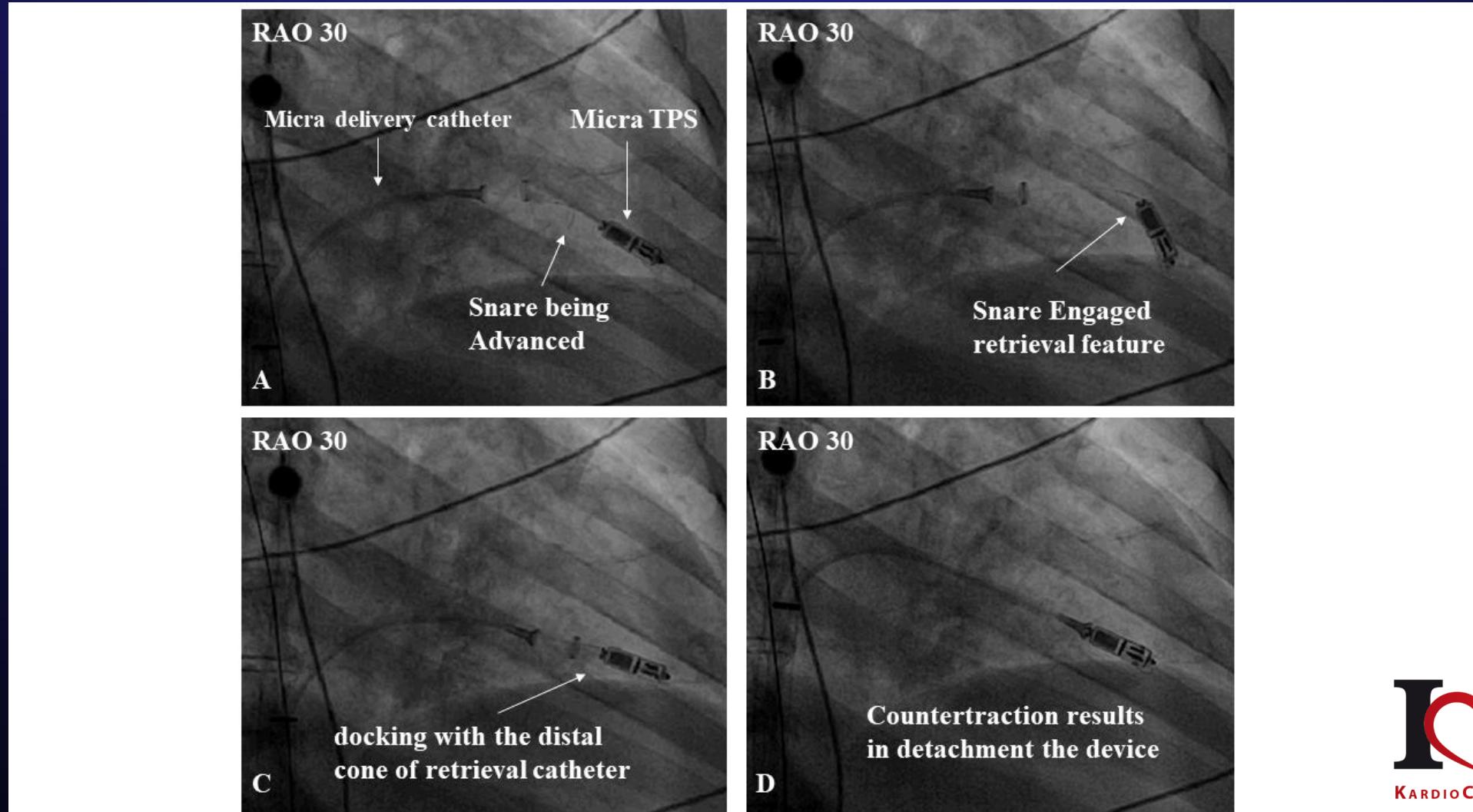
Princip adaptované Extrakce MICRA TPS



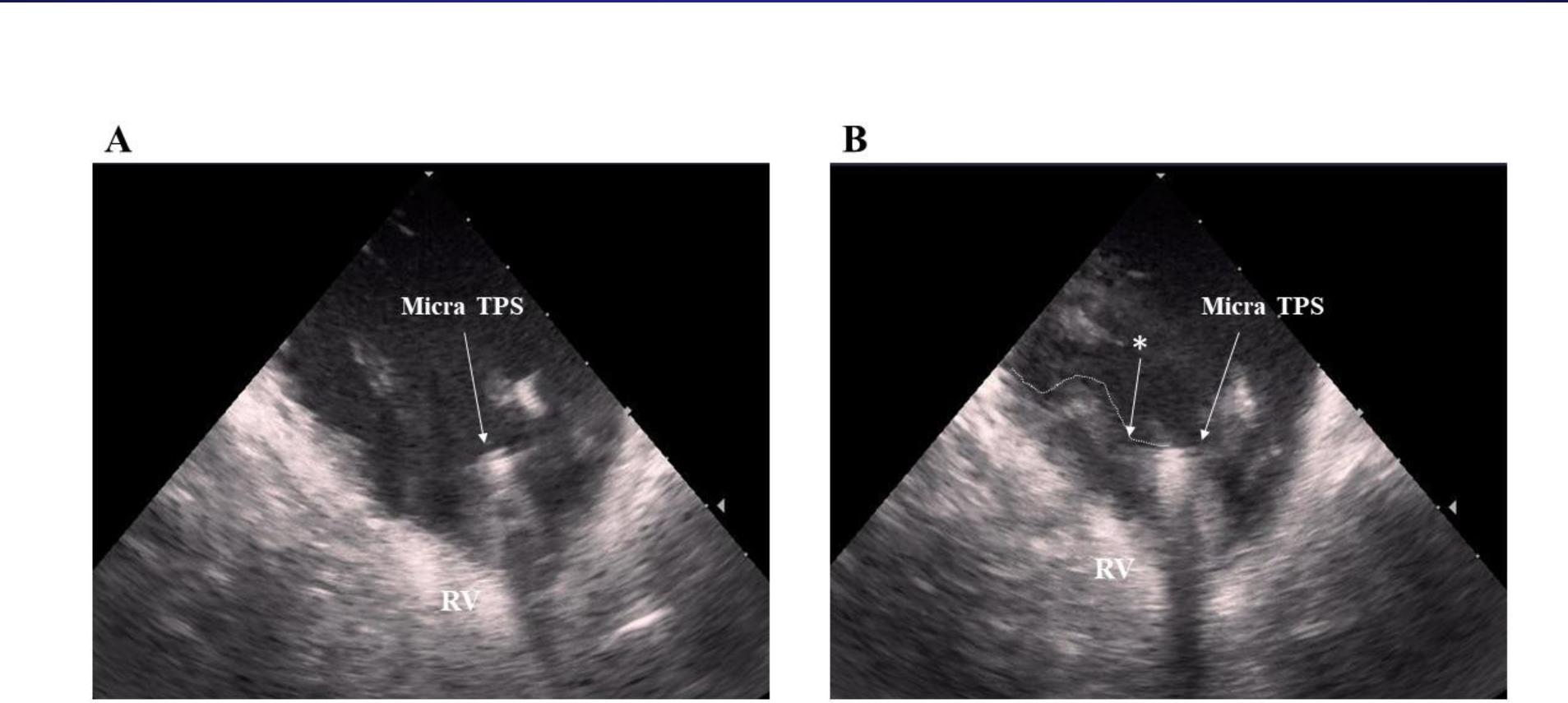
Princip adaptované Extrakce MICRA TPS



Princip adaptované Extrakce MICRA TPS



ICE monitorace Extrakce MICRA TPS



Minami K/Neuzil P et al: JACC Case Rep. 2020 Nov
18;2:2249-2252

Case Presentation

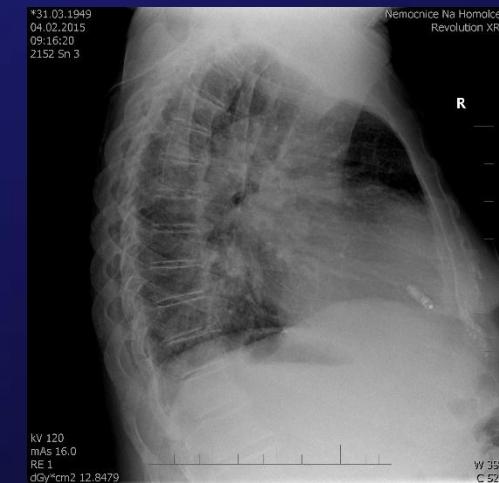
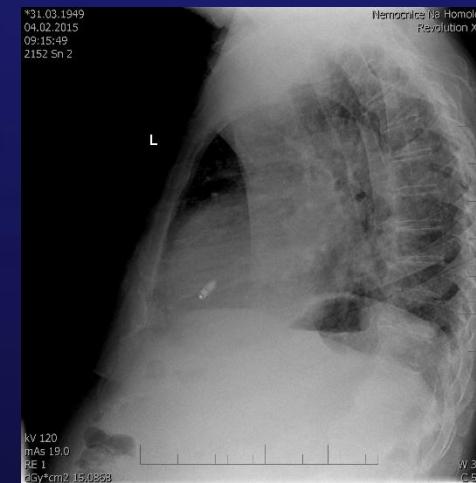
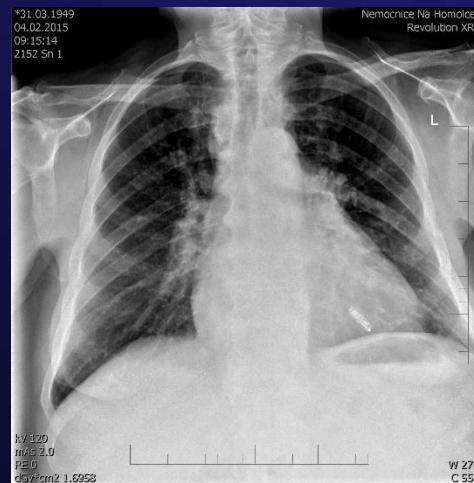
1.st world MICRA TPS retrieval – battery failure

- 65 year old male
- Medical history:
 - Permanent Afib slow response , CHA₂DS₂ VASc score 4
 - TPS MICRA Medtronic implantation in February 2015
 - Arterial hypertension
 - Hyperlipidemia
 - Diabetes mellitus type 2
 - COPD, moderate PA hypertension, borderline RV diameter
 - Stroke (cardioembolic etiology) 2004 and 2014
 - St.p. polypectomy for adenoma of colon in 2011
- Medications: warfarin, furosemid, kalium chloratum, ramipril, losartan, rosuvastatin, metformin, allopurinol

Case Presentation

1.st world MICRA TPS retrieval – battery failure

- TPS MICRA implanted February 3rd ,2015
- Difficult RV apex approach that required multiple repositions of the Micra device
- Next day follow up:
 - Increase of threshold (~3,5 V) with preserved sensing and impedance parameters
 - Transthoracic echocardiography and chest X-ray was performed with no sign of perforation or device displacement
 - Adequate energy output was set and prednison therapy was initiated



- Patient discharged : early follow-up was scheduled in Pacemaker clinic

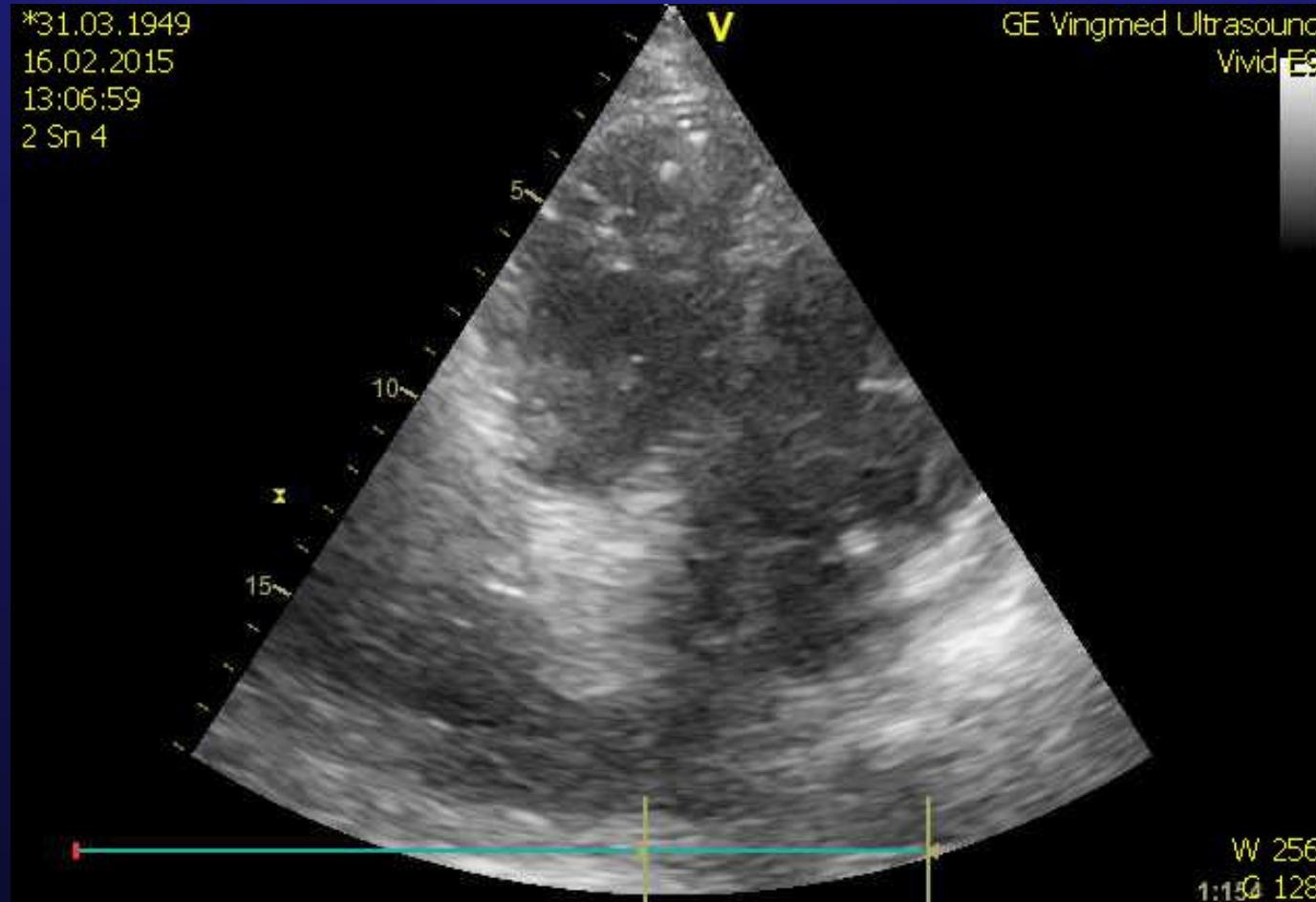
Case Presentation

1.st world MICRA TPS retrieval – battery failure

- 1st month:
 - Patient still in good condition
 - Improvement of pacing threshold: 4,38-3,38V/0,24ms
 - RV capture management activation, output set on 5V
- 3rd month:
 - Mild worsening of patients conditions – lower extremities fatigue, initial swelling
 - Increasing of pacing threshold – no capture on 3,63V/0,24ms
 - RV capture management set off, pulse width set back on 1,0 ms with output of 5V → still irregular capture on lower rate → capture only in rate over 110/min
- 6th month:
 - General worsening with swelling, ascites
 - Pacing threshold still high
 - Intermittent capture 5,0 V/0,24 ms
 - Holter monitoring
- Follow-up in 9/2015 and 2/2016 (12 months)
 - No improvement loss of capture detected by ECG monitor, Battery capacity - ERI
 - Decision for TPS Micra retrieval: **March 15th ,2016**

Case Presentation

1.st world MICRA TPS retrieval – battery failure



Echocardiography focused on RV

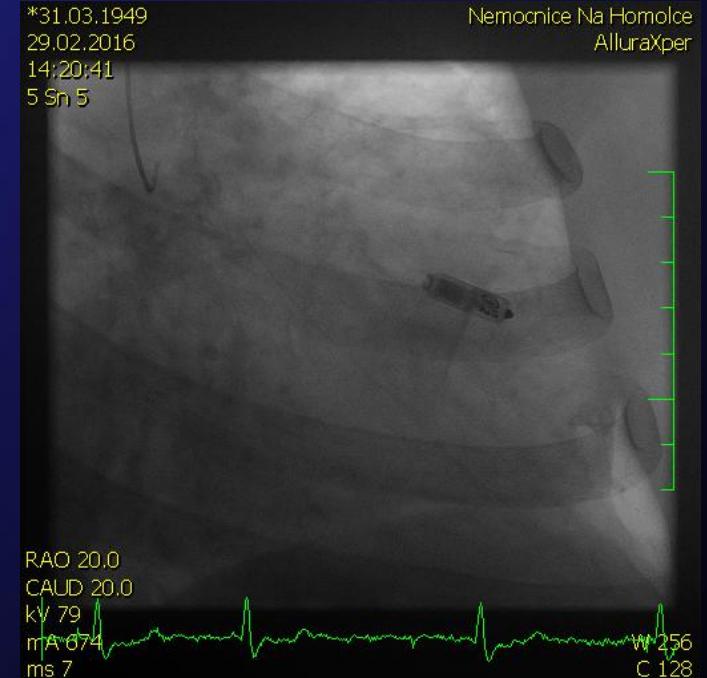
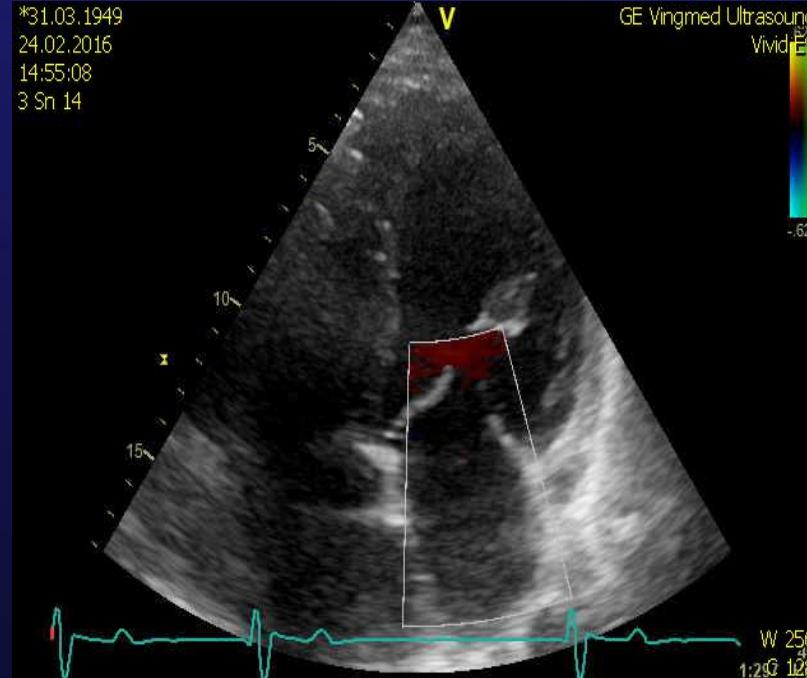
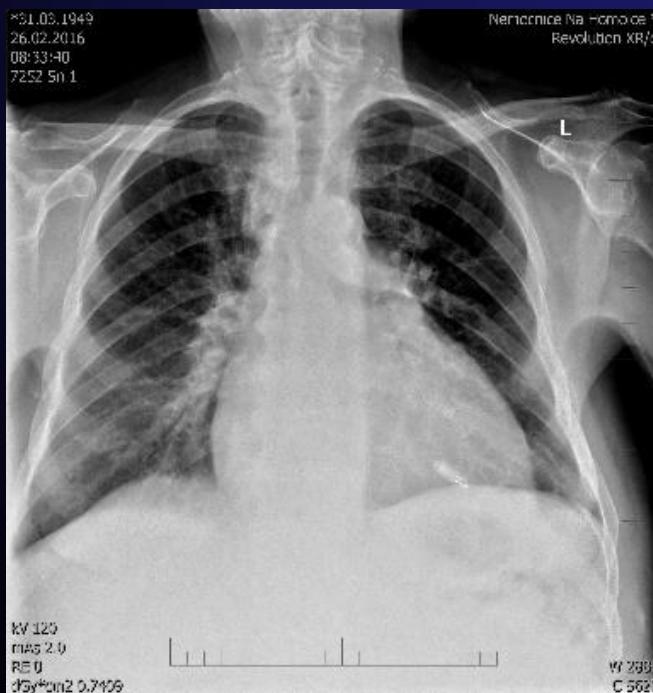
Case Presentation

1.st world MICRA TPS retrieval – battery failure

TTE:

Pulmonary hypertension with RV and RA dilation
No significant valve disease

CT AG and VP scan: Excluded pulmonary embolism
Coronary angio: Minimal atherosclerotic changes



Case Presentation

1.st world MICRA TPS retrieval – battery failure



Retrieval after 395 days



Case Presentation

1.st world MICRA TPS retrieval – battery failure

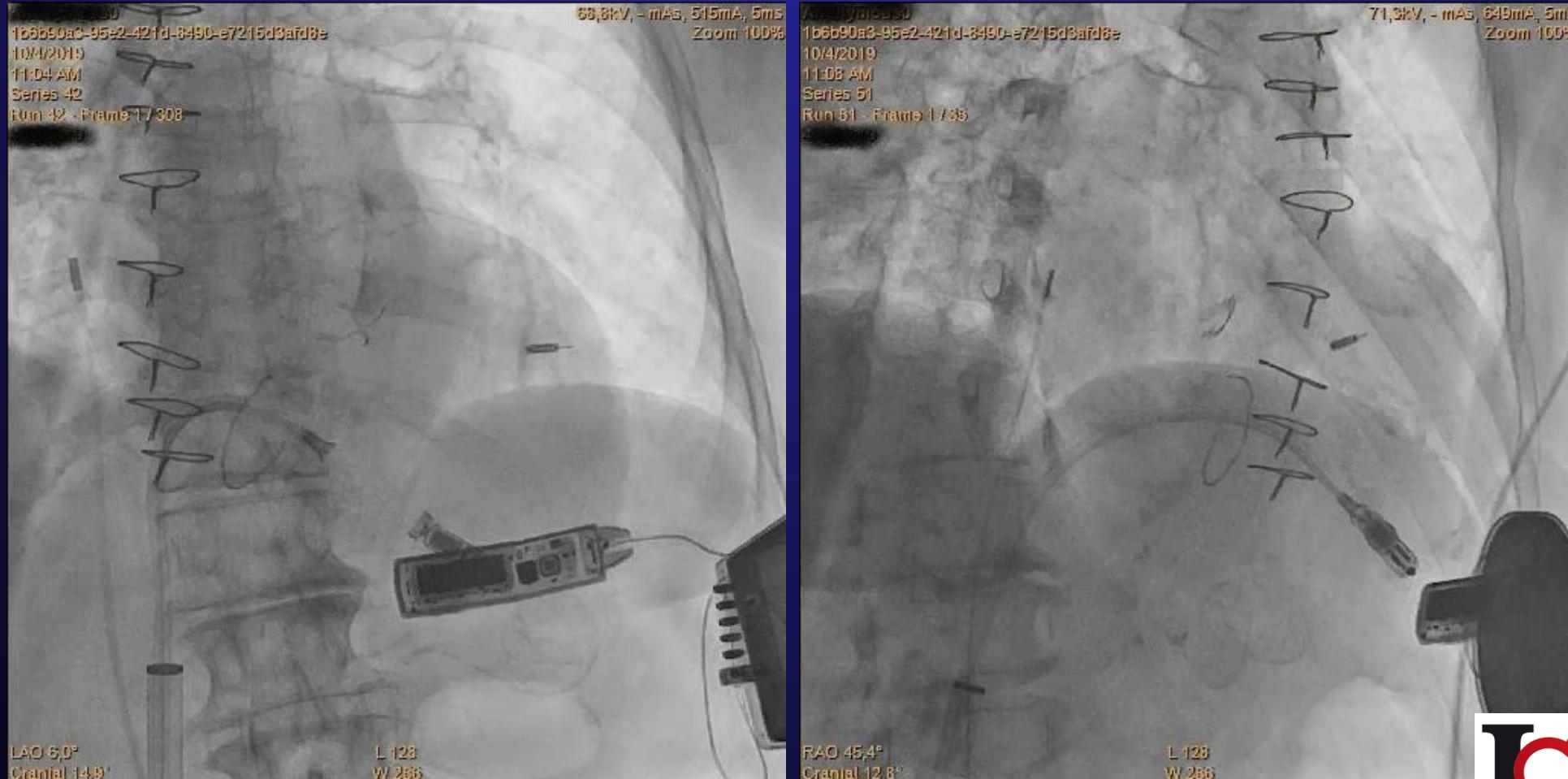
Retrieval after 395 days



Minami K, Petrů J, Neuzil P J. Clinical Cardiol Cardiovascular Interv. 2021; 4(6); Doi:10.31579/2641-0419/138

Case Presentation

MICRA TPS retrieval in WICS CRT Patient



Minami K/Neuzil P et al: JACC Case Rep. 2020 Nov 18;2:2249-2252

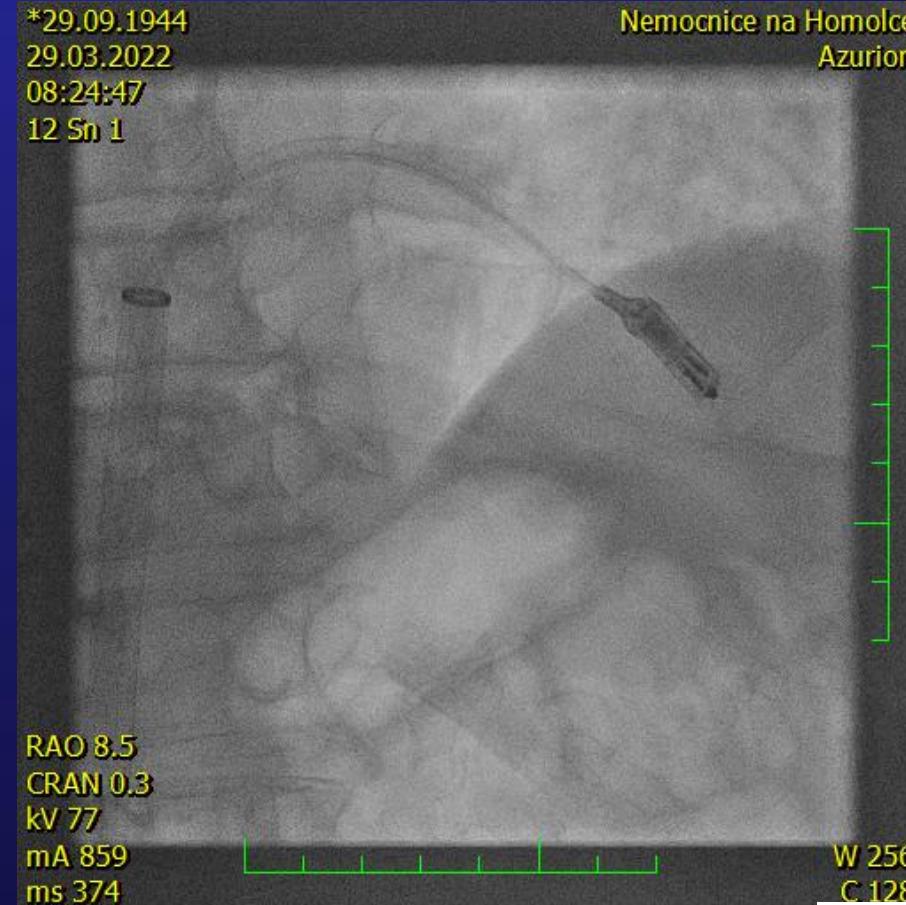
Case Presentation

MICRA TPS retrieval in WICS CRT Patient



Extrakce MICRA TPS

~ 7 let po primoimplantaci



19.2.2014 implantace MICRA leadless KS

29.3.2022 extrakce a reimplantace nového leadless KS Micra VR

Extrakce MICRA TPS

~ 7 let po primoimplantaci

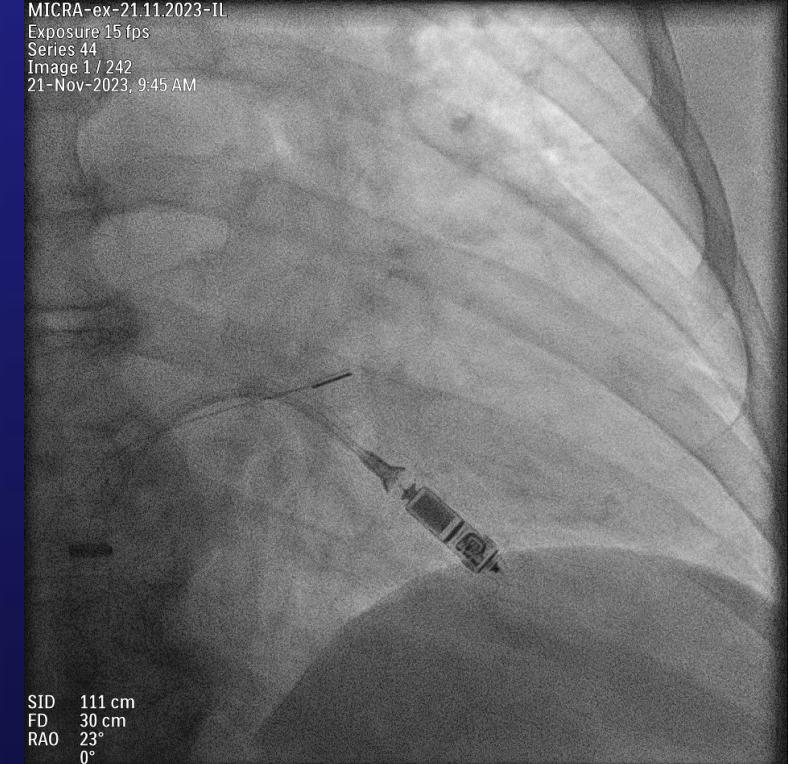
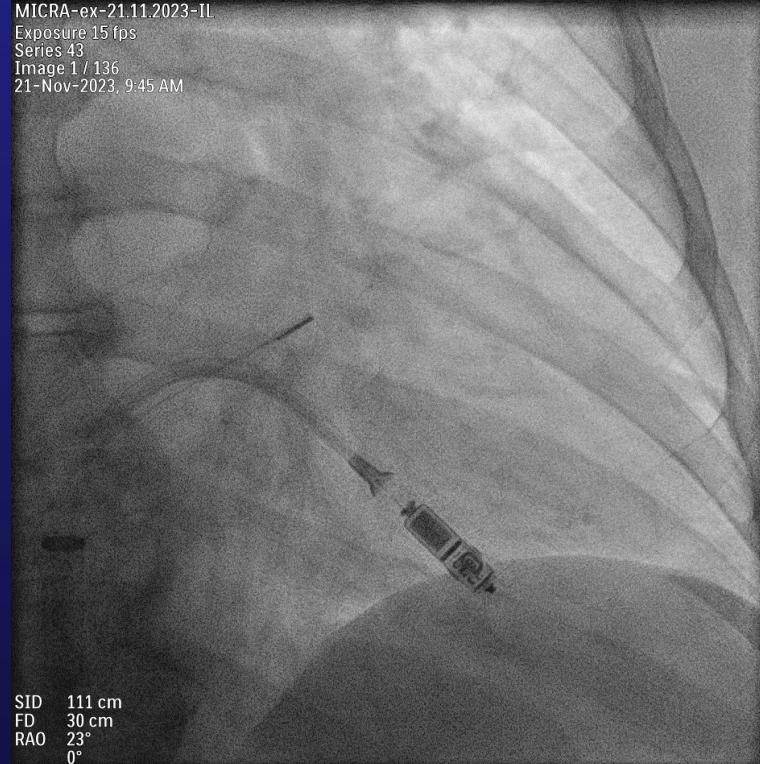
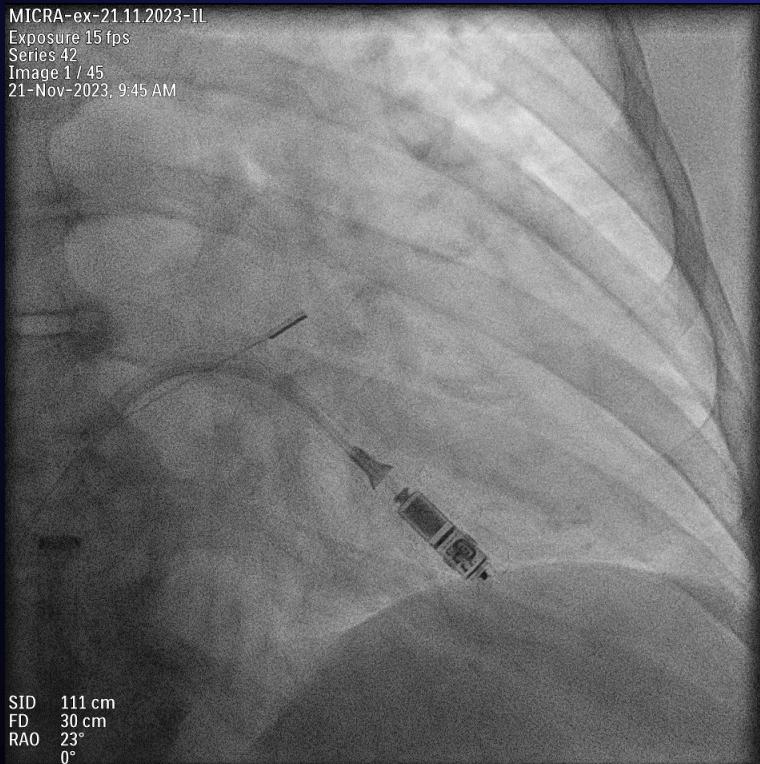


Delivery katetr se zavedenou kličkou – Ø 7 mm → kontratrakcí uvolnění kotev (10 min.)

Nekomplikovaná re-implantace nového přístroje Micra VR - excellentní parametry

Extrakce MICRA TPS

~ 9 let po primoimplantaci



Extrakce MICRA TPS

~ 9 let po primoimplantaci

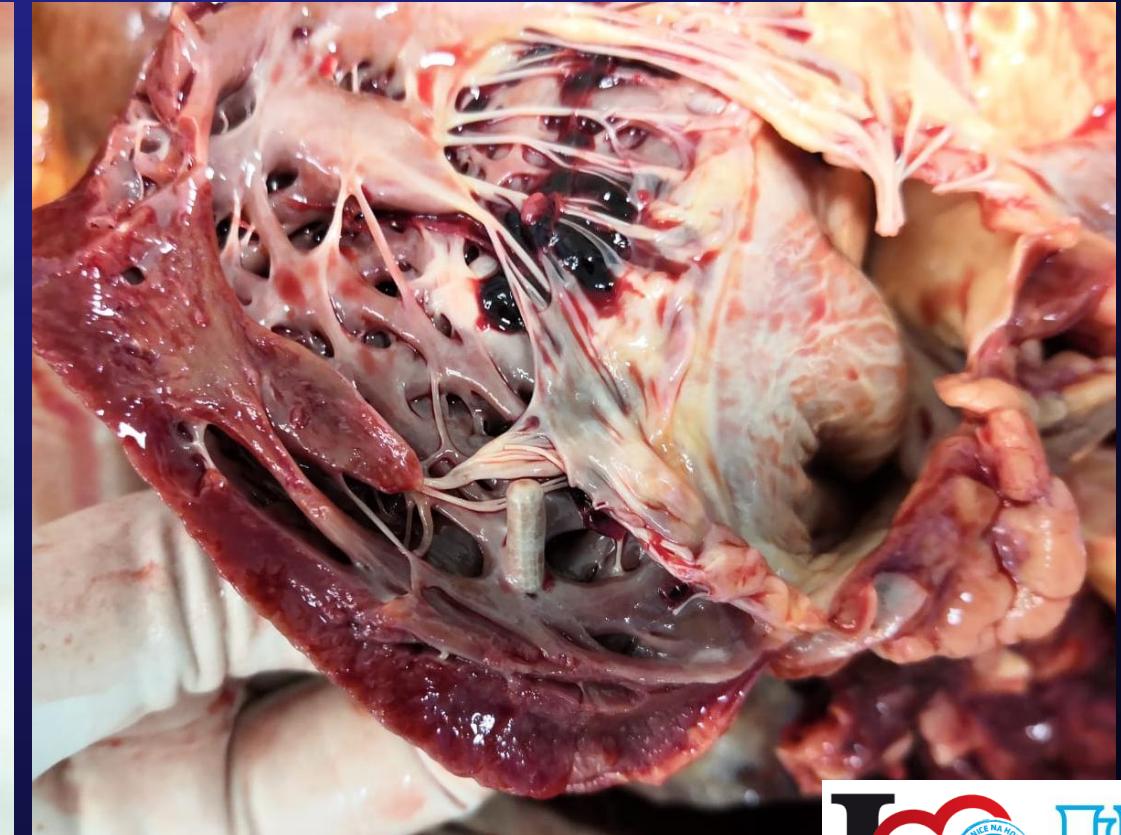
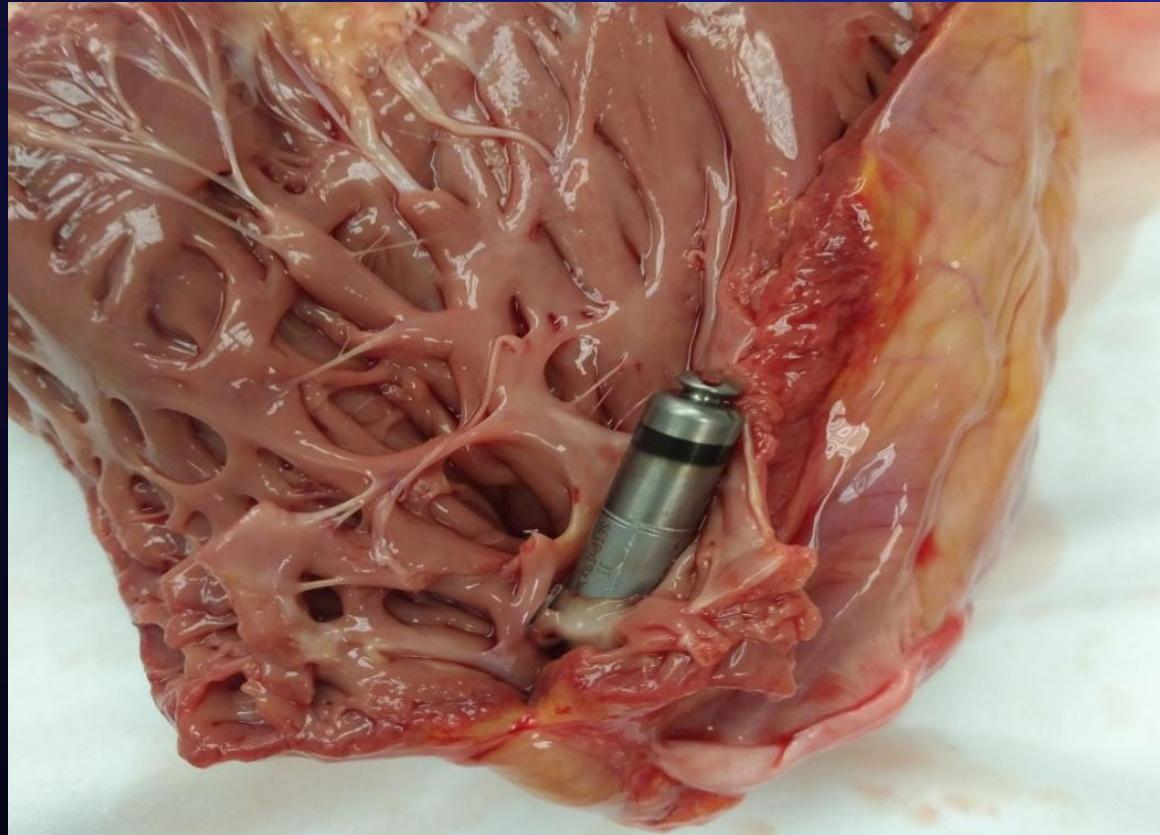


MICRA PO EXTRAKCI:

Minimální tkáňové srůsty kolem vlastní kapsle přístroje

Autopsy of Micra TPS and WiSE

Both Devices 2 years after implantation



Extrakce Leadless Homolka

- Celkem byla extrakce provedena u **61 nemocných** s leadless stimulací
- **52 Nanostim LCP, 9 Micra TPS, 1 Aveir VR, 1 Aveir AR.**
- Průměrný věk nemocných byl **$72,5 \pm 17$ let**
- Průměrná doba od implantace **1496 ± 482 dní**
- Úspěšnost extrakce LCP Nanostim ($47/51 = 92\%$)
- Úspěšnost extrakce Micra TPS ($7/8 = 87,5\%$)
- Oba dva Aveir VR/AR byly extrahovány po několika měsících..
- Nový system leadless KS byl implantován u většiny nemocných (**n 58 = 90%**) v jedné době po provedené extrakci.

ÚSPĚŠNOST EXTRAKCE MICRA TPS

	VĚK (roky)	M/Ž	Doba od impl. (dny)	Čas skia (minuty)	ÚSPĚCH	Indikace	Reimpl.
1	82	M	280	37	ANO	BATERIE	MICRA
2	54	M	777	21	ANO	PM SYN.	DDD
3	66	Ž	406	13	ANO	< EF LK	CRT-D
4	46	M	287	49	NE	< EF LK	CRT-D
5	79	M	1219	15	ANO	BATERIE	MICRA
6	49	Ž	360	12	ANO	PM SYN.	DDD
7	36	Ž	2959	6	ANO	BATERIE	MICRA
8	62	M	956	14	ANO	< EF LK	CRT-P
Ø	59±15		905,5±426	39,3± 12			

ZÁVĚRY

- Extrakce dlouhodobě implantovaného systému leadless MICRA TPS je schůdná a bezpečná i při adaptovaném použití „of label“ systému, který není původně určen k provádění extrakce
- Reimplantace nového MICRA TPS leadless kardiostimulátoru je efektivní
- Naše vlastní zkušenosti vedou ke zdokonalení techniky námi metodiky extrakce
- Extrakce MICRA TPS by měla být z klinického pohledu zvažována a je otázkou, zda má být zahájen vývoj nové metody extrakce

Konflikt zájmů

- Konzultant & podpora výzkumného grantu:

- Abbott Inc.
- Medtronic Inc.
- EBR Inc.
- Boston Scientific Inc.
- Cairdac Inc.



10 LET PO PRVNÍ IMPLANTACI NENÍ LEADLESS KARDIOSTIMULACE SVÉBYTNOU PLATFORMOU



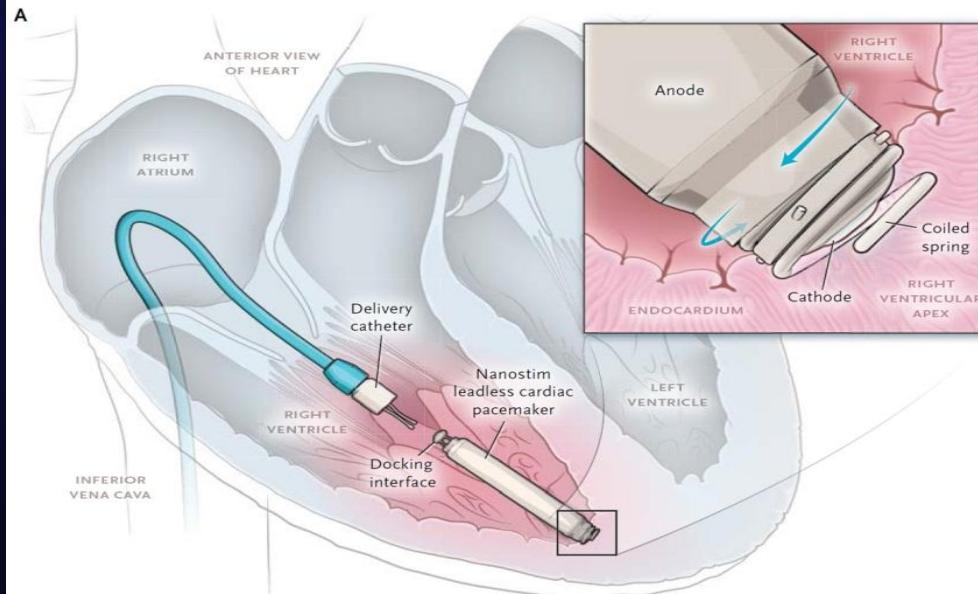
„LEADLESS“_EVIDENCE BASED MEDICINE

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 Plunkett, M.D., Rajesh Bunker, M.D.,
James Porterfield, M.D., James E. Ip, M.D., and Srinivas R. Dukkipati, M.D.,
for the LEADLESS II Study Investigators*



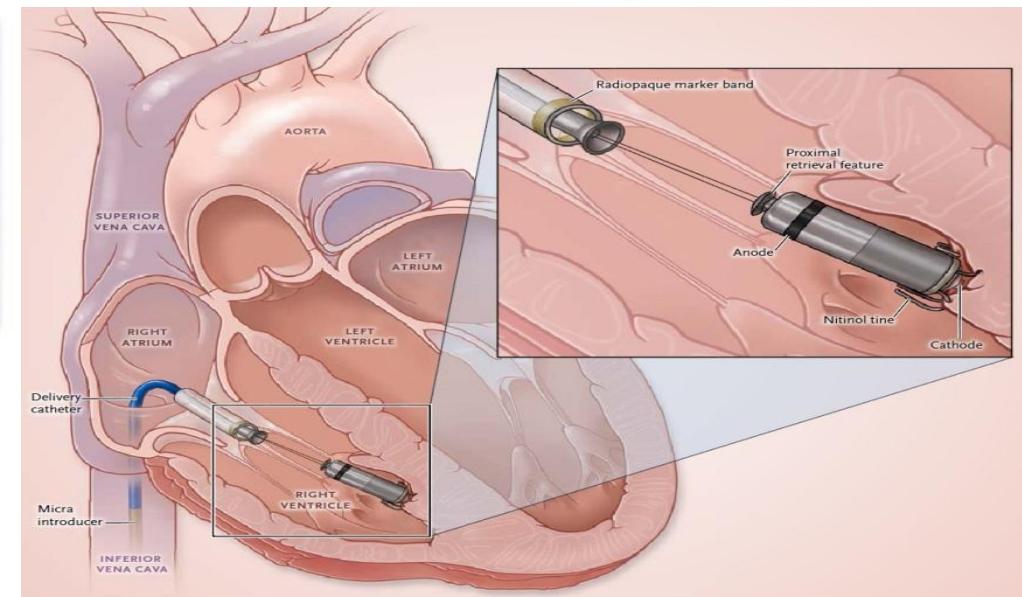
Reddy VY et al: NEJM 2015, Sept 17, 373: 1127.

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 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*



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

Hlavní výzvy „leadless“ technologie

- Fixation Technology
 - Superior holding force
 - Increased electronic packaging density
 - Novel power sources
 - Ultra low power circuitry
 - Electrode-tissue interface; low, stable pacing thresholds
 - VVIRw/Hysteresis
 - Inherently MRI compatible
-
- ◆ Communication systems:
 - Inter-device (intrabody)
 - ◆ Atrial Component for DDD:
 - Fixation and stability
 - ◆ Catheter based acute/chronic retrieval
 - ◆ Additional chambers
 - Leadless PM for LV
 - ◆ Integrated S-ICD/Leadless system for pacing and ATP

Nemocnice Na Homolce: zkušenosti jednoho centra

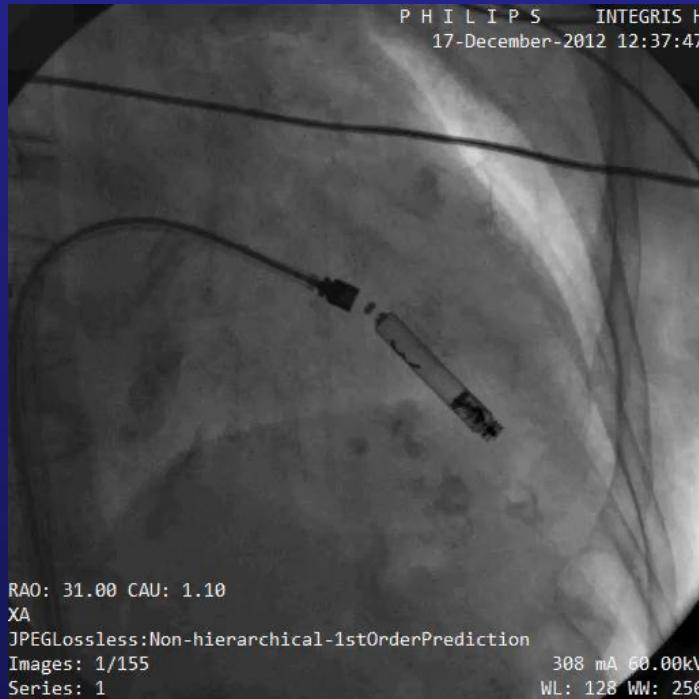
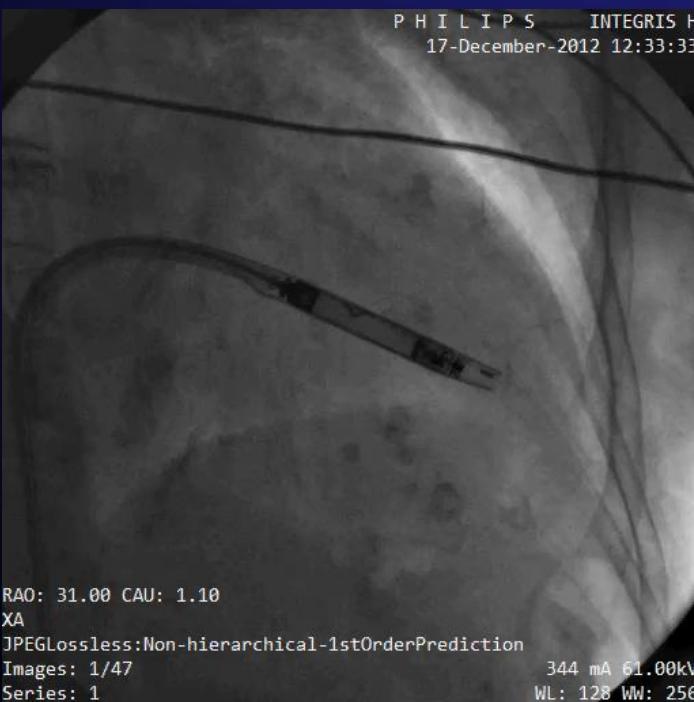
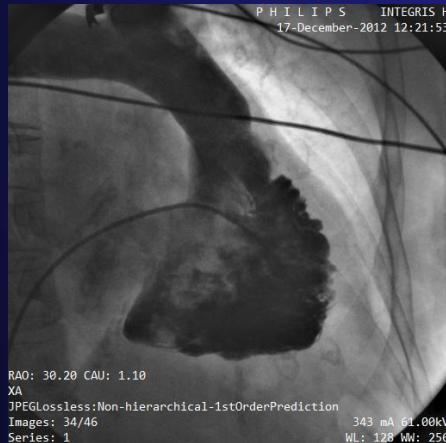
Leadless pacing v NNH: 2012 - 2021	
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Jiná než VVI stim.	4x (2 x leadless + WiCS, 2 x leadless + S-ICD)
Komplikace	0,9% 4 dislokace 0,2% 1 srdeční tamponáda 0 % revize třísla, infekce, smrt

Kazuistika

- 84 letá žena, BMI 21.6, long-standing perzistentní FiS (CHA2DS2-VASc 4), antikoagulace Pradaxa (2 x 150 mg)
- Nanostim LCP (St Jude Medical Inc) implantace: Prosinec 17,2012, s optimálními elektrickými parametry.
Stabilní během kontrol až do listopadu 2021, kdy nebylo možné LCP načíst – indikace : status baterie EOL.
- Po měsíci od poslední kontroly byla přijata k provedení extrakce LCP. Kontrolní RTG skiaskopie zachovaný pohyb implantovaného LCP: „swinging movement“ fenomén predikce úspěšné extrakce

Kazuistika

Implantace Nanostim LCP 17.12.2012

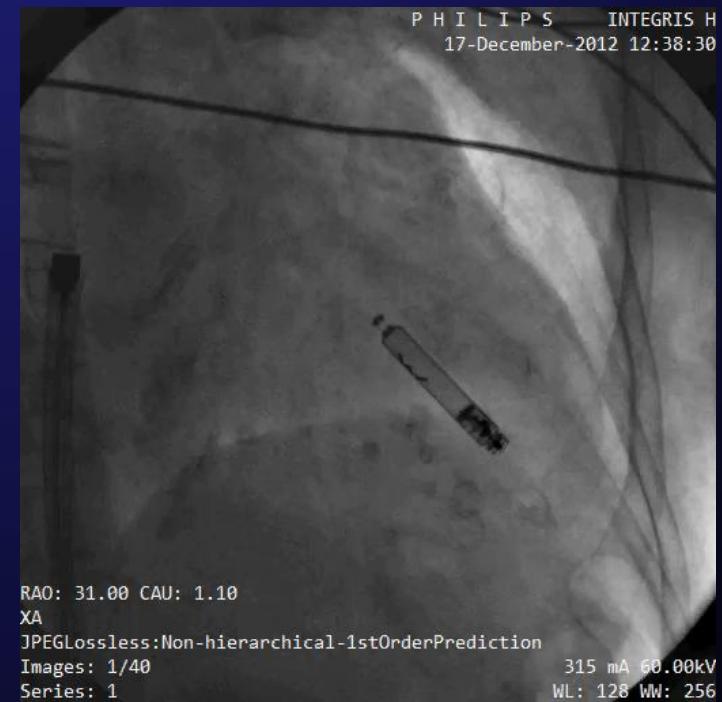


Akutní stim. práh 0.5 V @ 0.4ms

Impedance 500 Ohm

Amplituda R vlny 7.5 mV

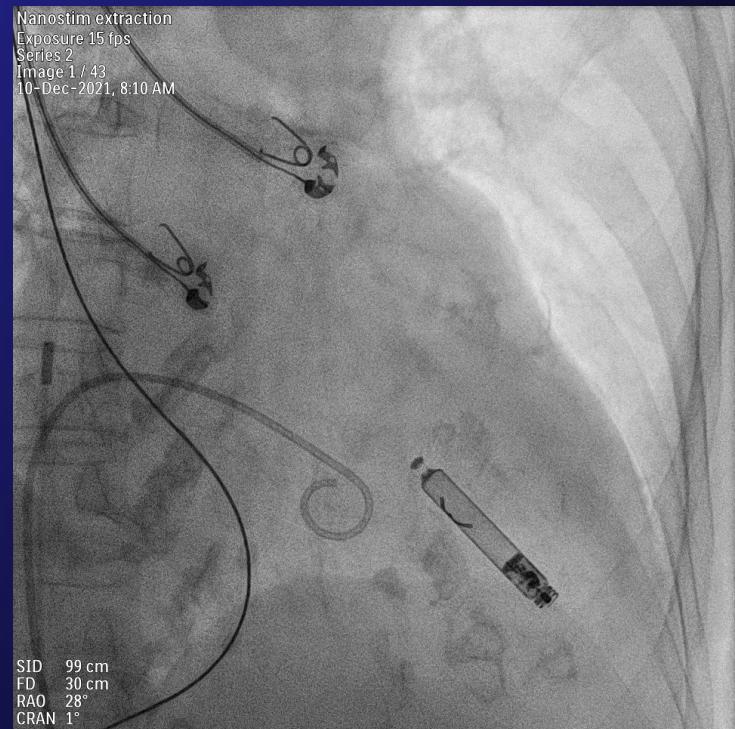
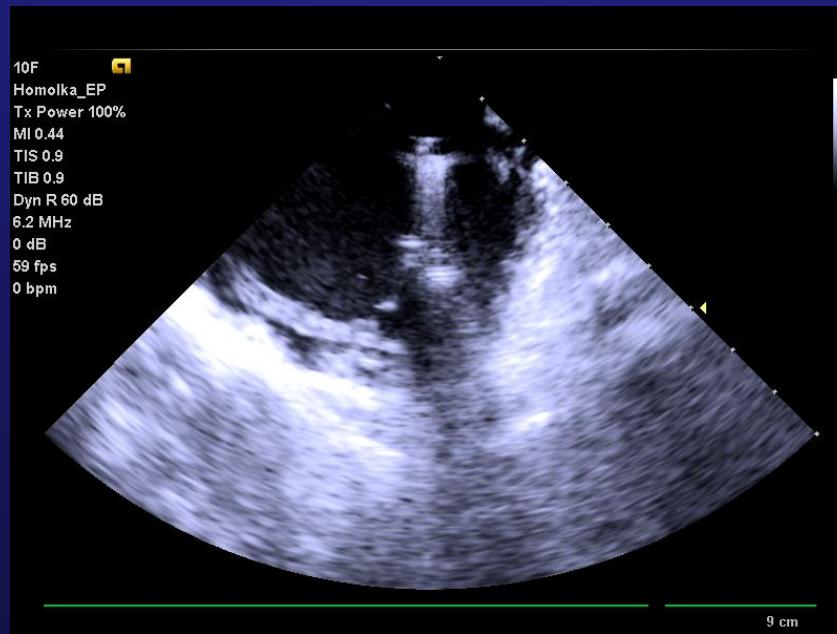
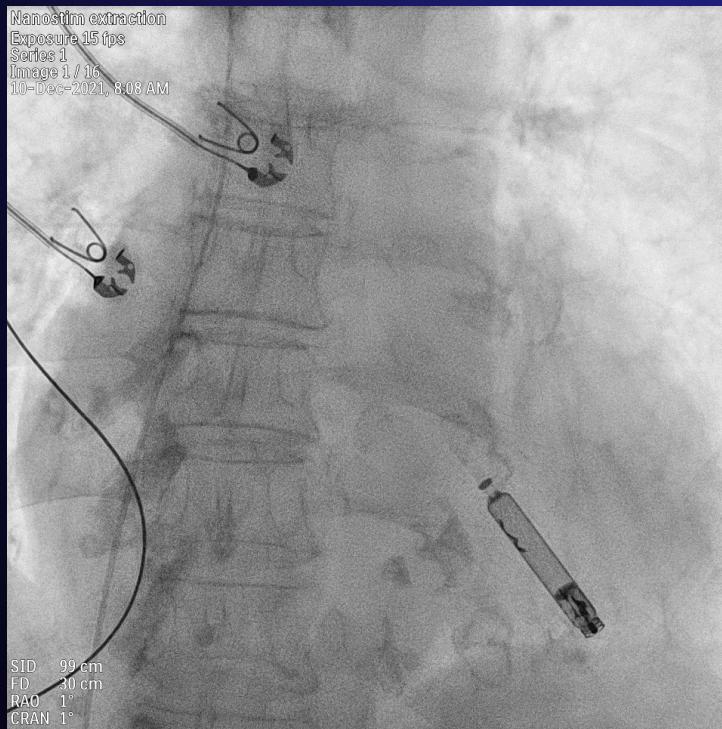
Bez komplikací



Kazuistika

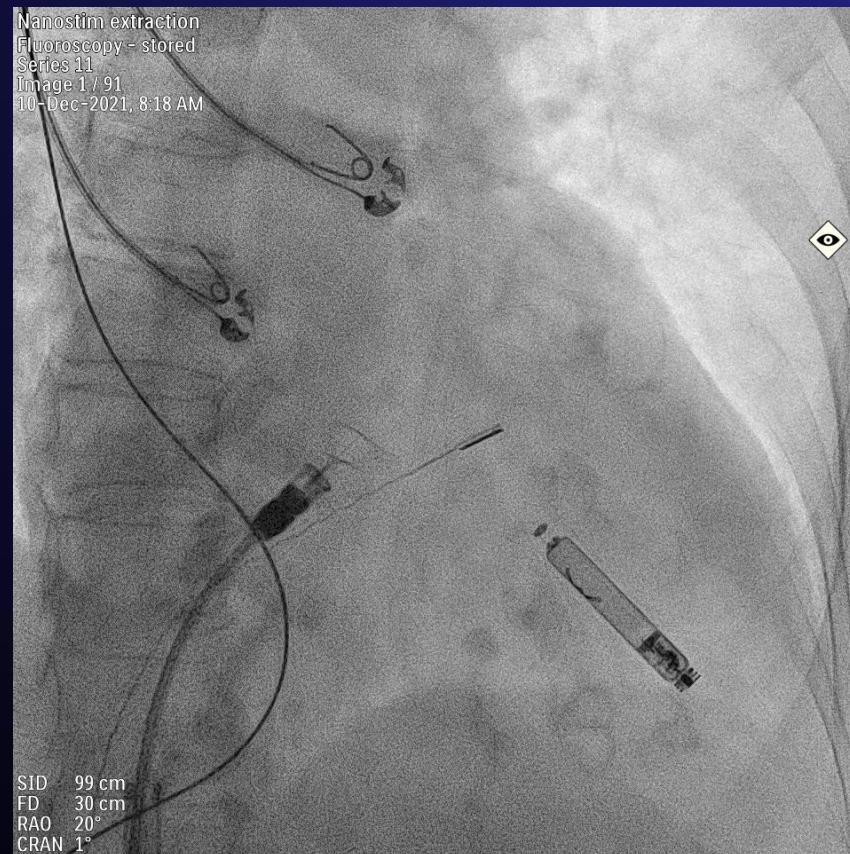
Extrakce Nanostim LCP 10.12.2021

10.12.2021, 08:08

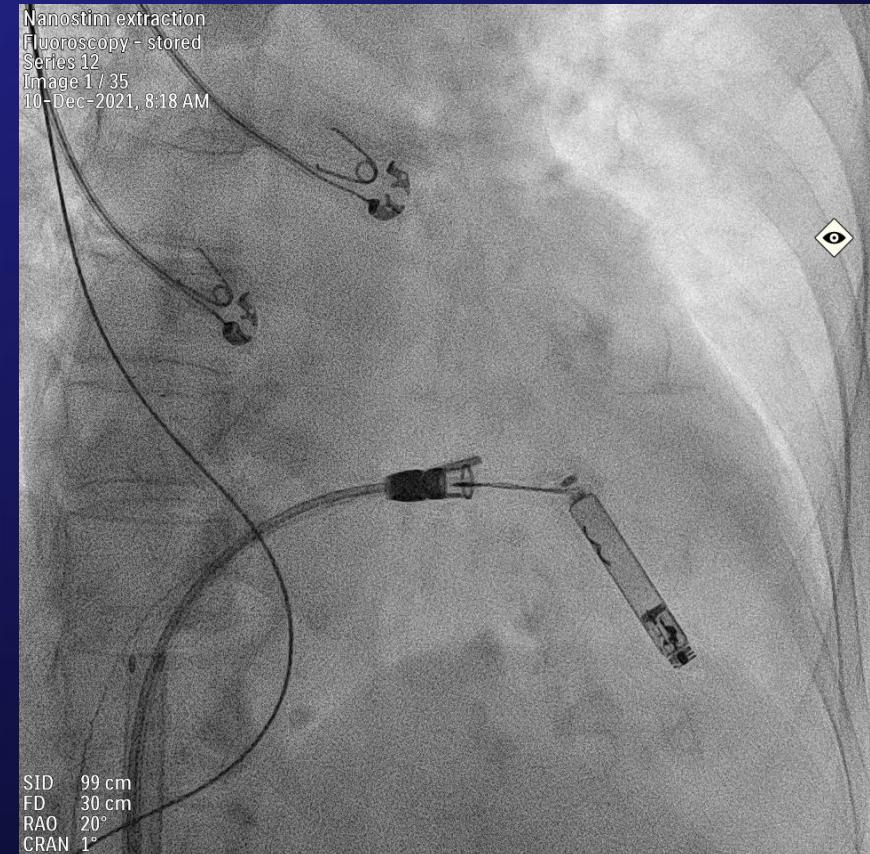


„Swinging „LP pohyb indikuje dobrou predikci úspěšná extrakce Nanostim LCP , aplikace kontrastní látky prakticky vylučuje adheze s okolní tkání

Tri-Loop High Torque retrieval katetr
CAPTURE 10.12.2021, 08:18



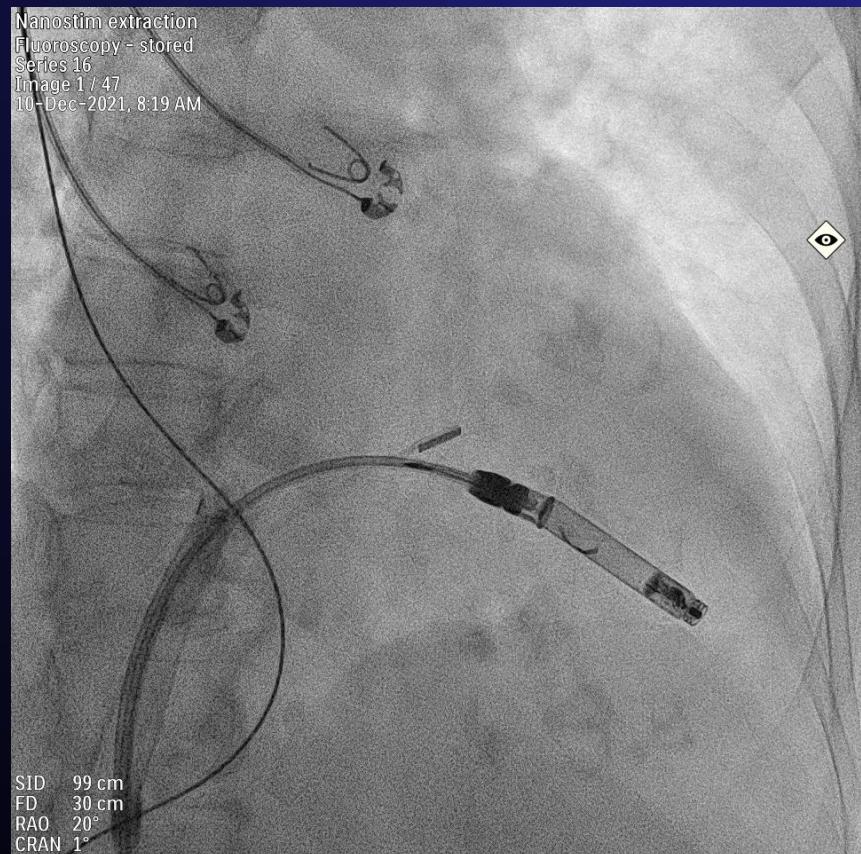
Tri-Loop High Torque retrieval katetr
DOCKING 10.12.2021, 08:18



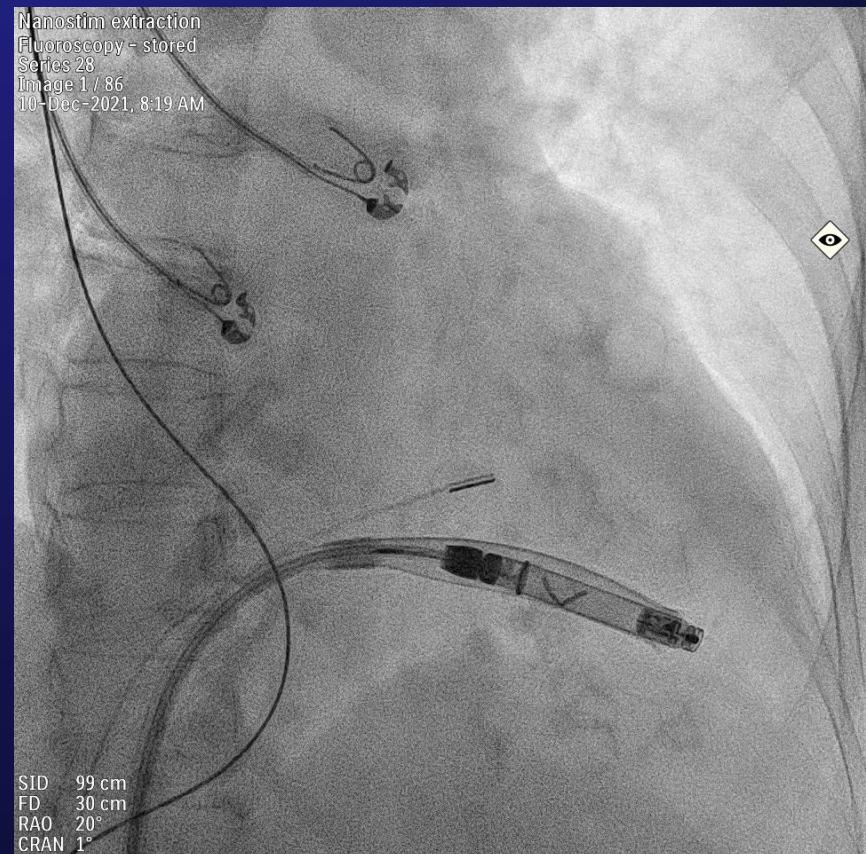
Kazuistika

Extrakce Nanostim LCP 10.12.2021

„Sleeve“ volný průchod
OVER LCP 10.12.2021, 08:19



Rotace a uvolnění Nanostim LCP
10.12.2021, 08:19

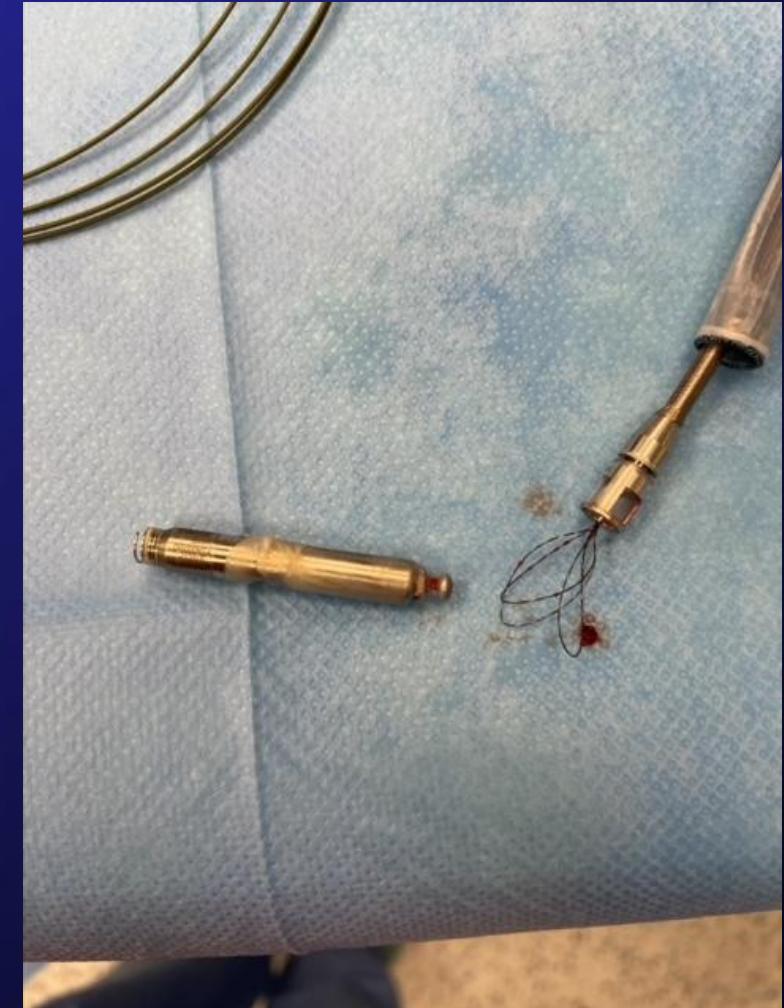




After Nanostim LCP retrieval:

Minimum tissue remnants on LP device body

No signs of tissue on the fixation knob and screw as well



Kazuistika

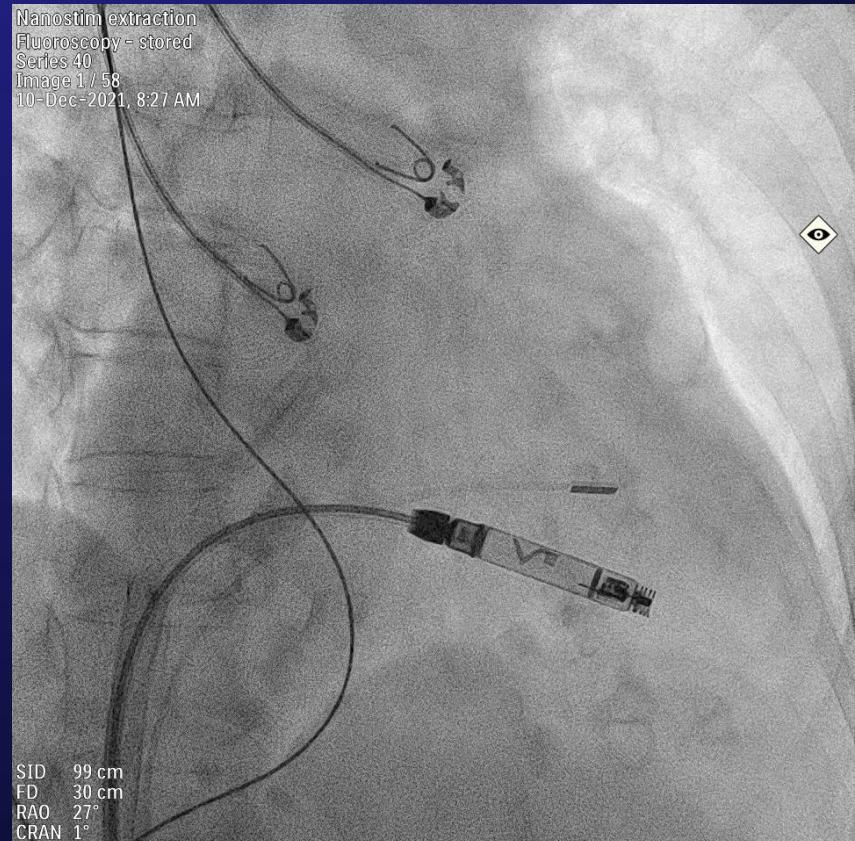
Implantace Aveir VR 10.12.2021

Zavedení přes TCH do PK
AVEIR VR 10.12.2021, 08:26

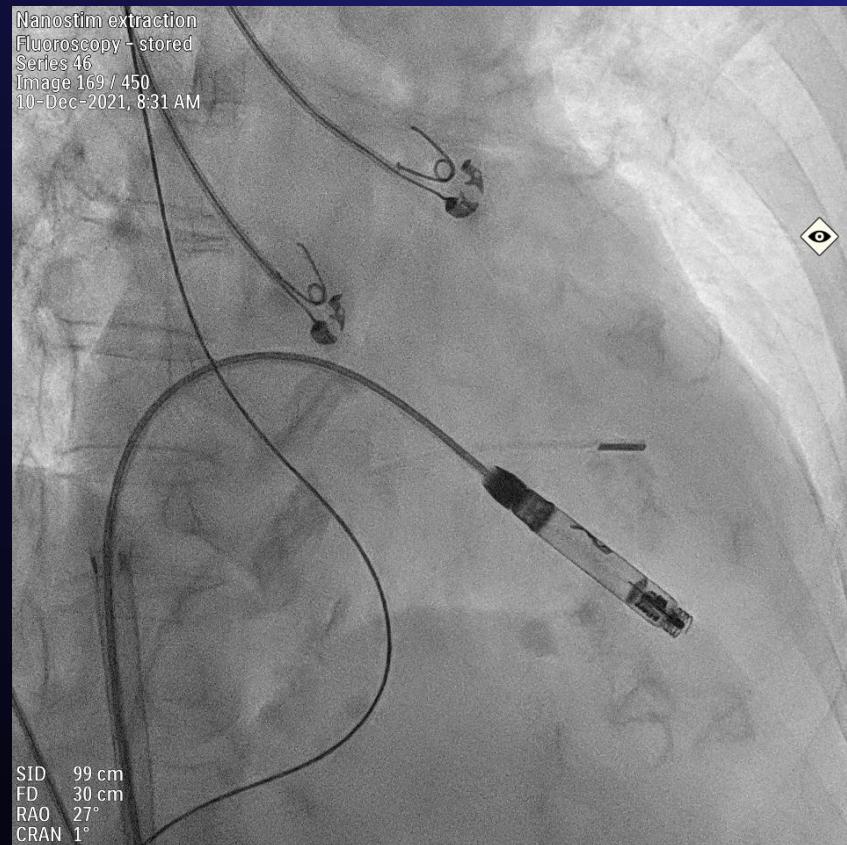


**Aveir VR:
Vícečetná repozice
nového LP
Aveir VR v různých
místech PK**

Repozice AV rámci PK
AVEIR VR 10.12-2021, 08:27



Fixace AVEIR VR v PK pomalá rotace 10.12.2021, 08:31



**Aveir VR:
Jednoduchá
implantace**

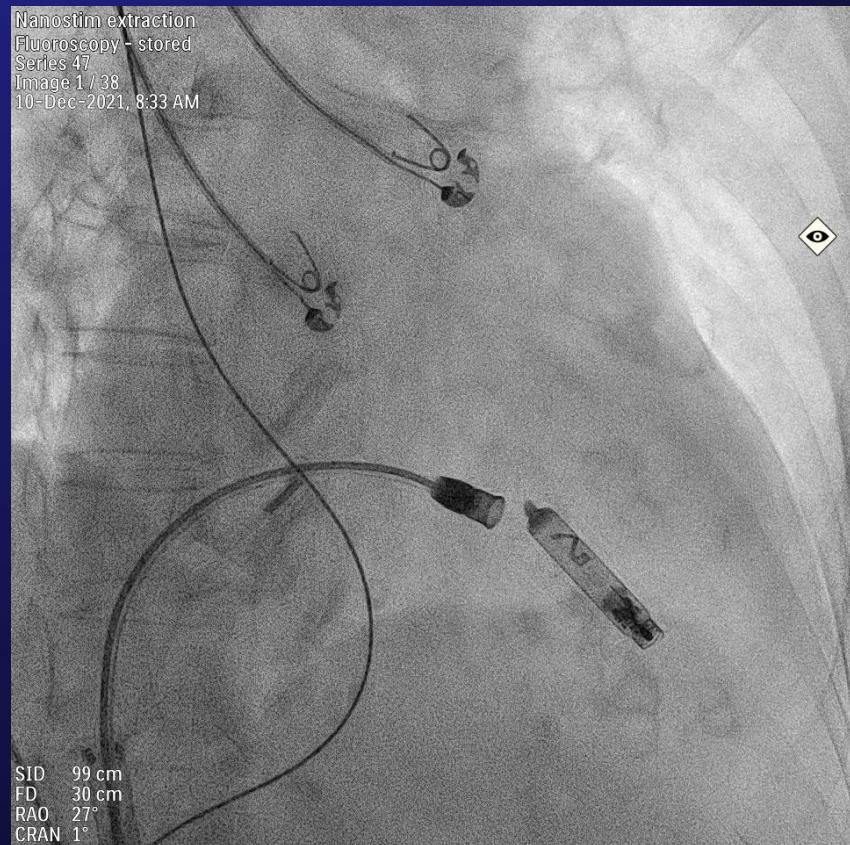
**Vyšší akutní
prahové hodnoty:**

2,5 V/0,4 ms

**Po čekací době
4 minuty:**

**1,0 V/0,4 ms
Impedance 630 Ω
R vlna 9 mV**

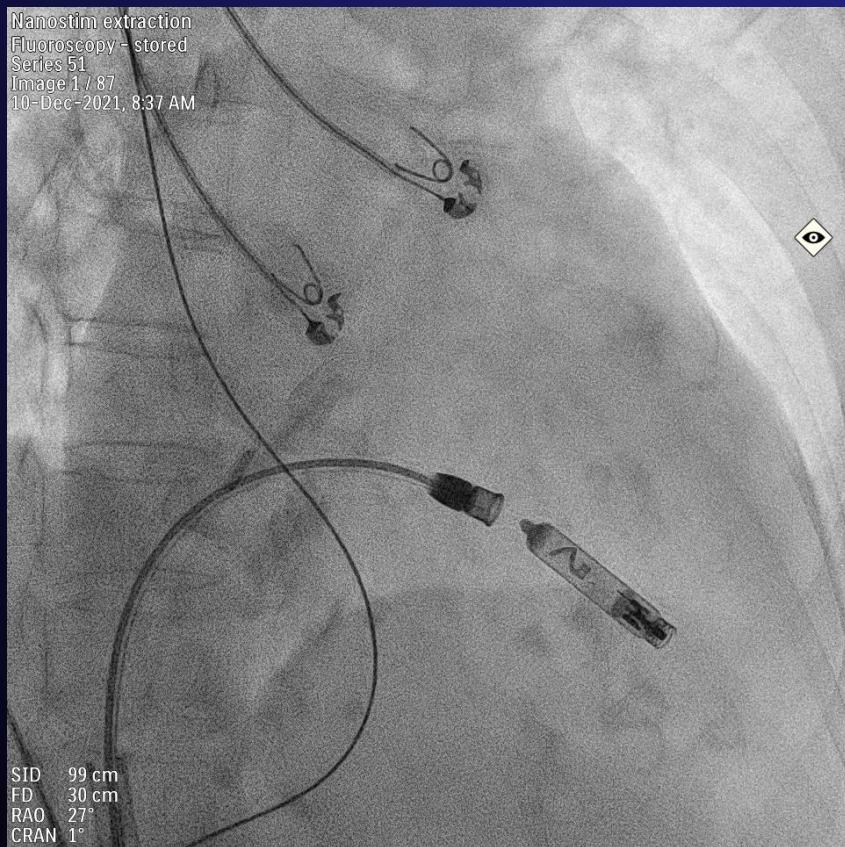
Test stability AVEIR VR 10.12.2021, 08:33



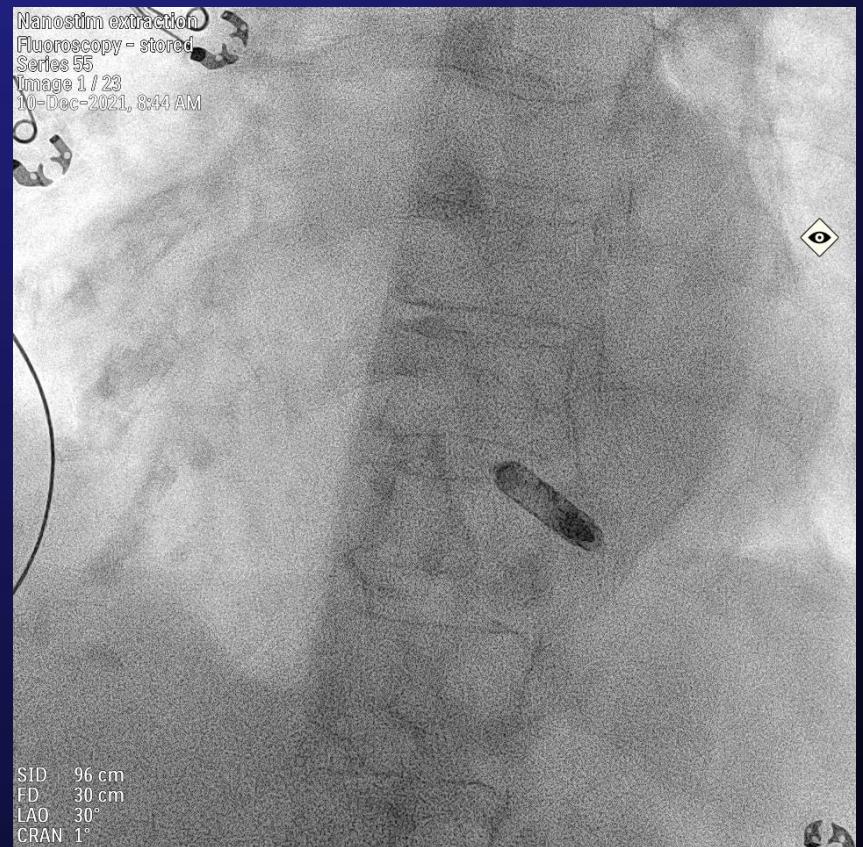
Kazuistika

Implantace Aveir VR 10.12.2021

**Konečná poloha a uvolnění
AVEIR VR 10.12.2021, 08:37**

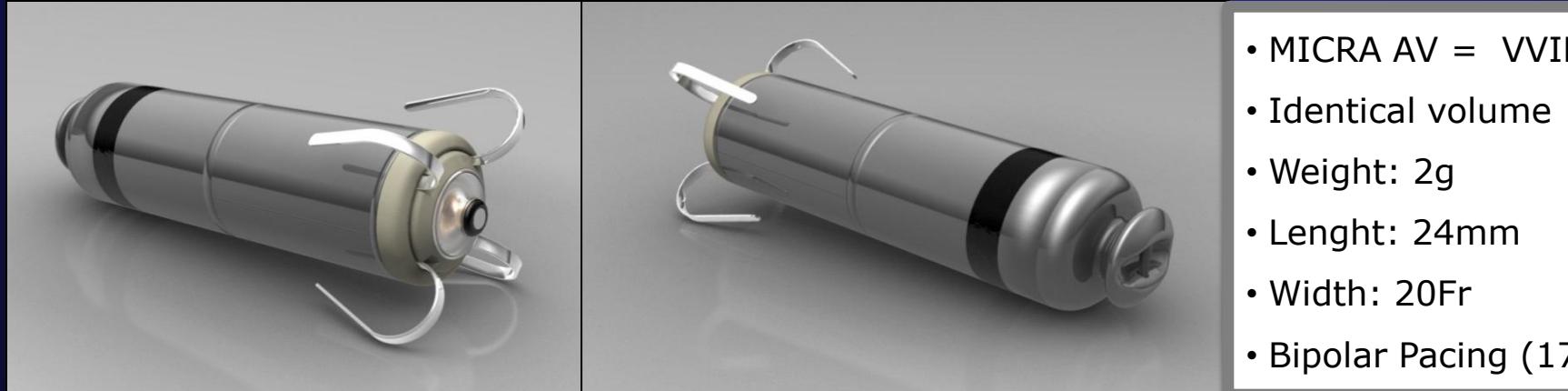


**Finální pozice před překladem ze sálu
AVEIR VR 10.12.2021, 08:44**



Fyziologická jednodutinová stimulace

Micra AV : od VVI k DDD



- MICRA AV = VVIR →VDD(R)
- Identical volume : 0.75ml
- Weight: 2g
- Length: 24mm
- Width: 20Fr
- Bipolar Pacing (17mm)

Micra Atrial TRacking Using a Ventricular AccELerometer Study (MARVEL) NCT03157297

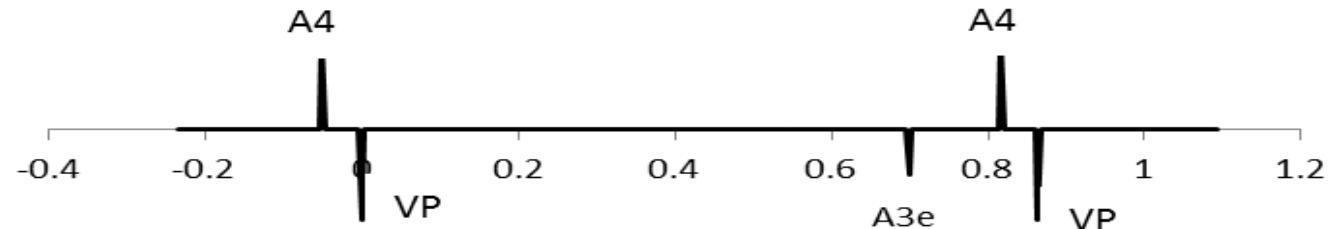
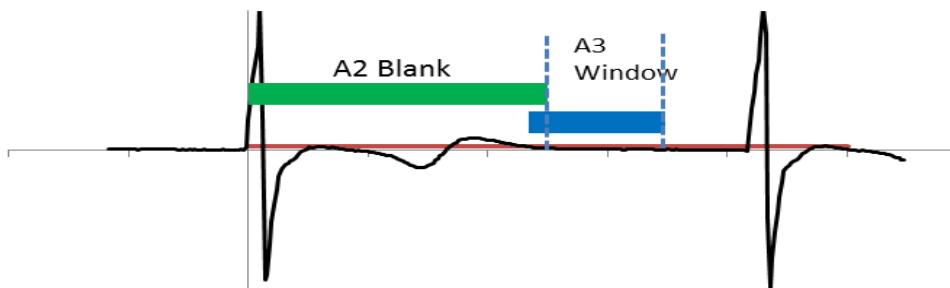
Primary Endpoint :

Synchronisation of ventricular pacing to reach = VDD

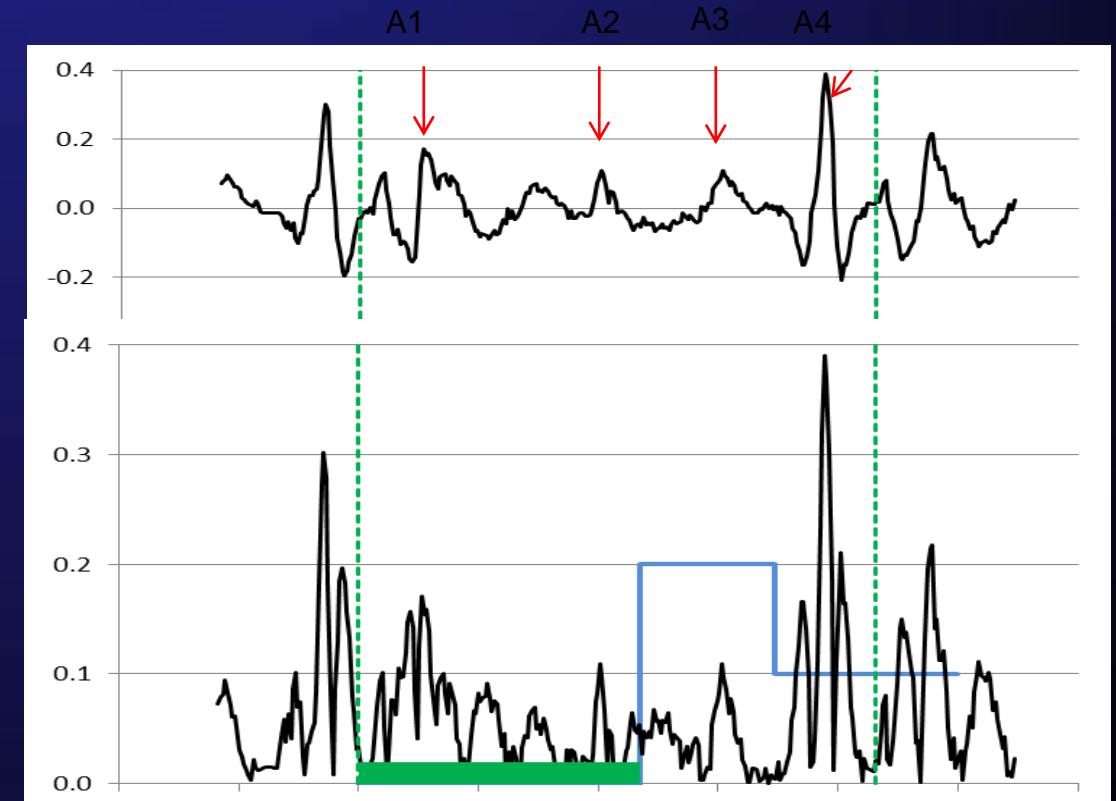
3 preexisting accelerometers : atrial activity detection based on tricuspid valve movement detection – in concert with P wave detection on ECG

Micra AV : VDD mode

Detekce pohybu cípu TCH



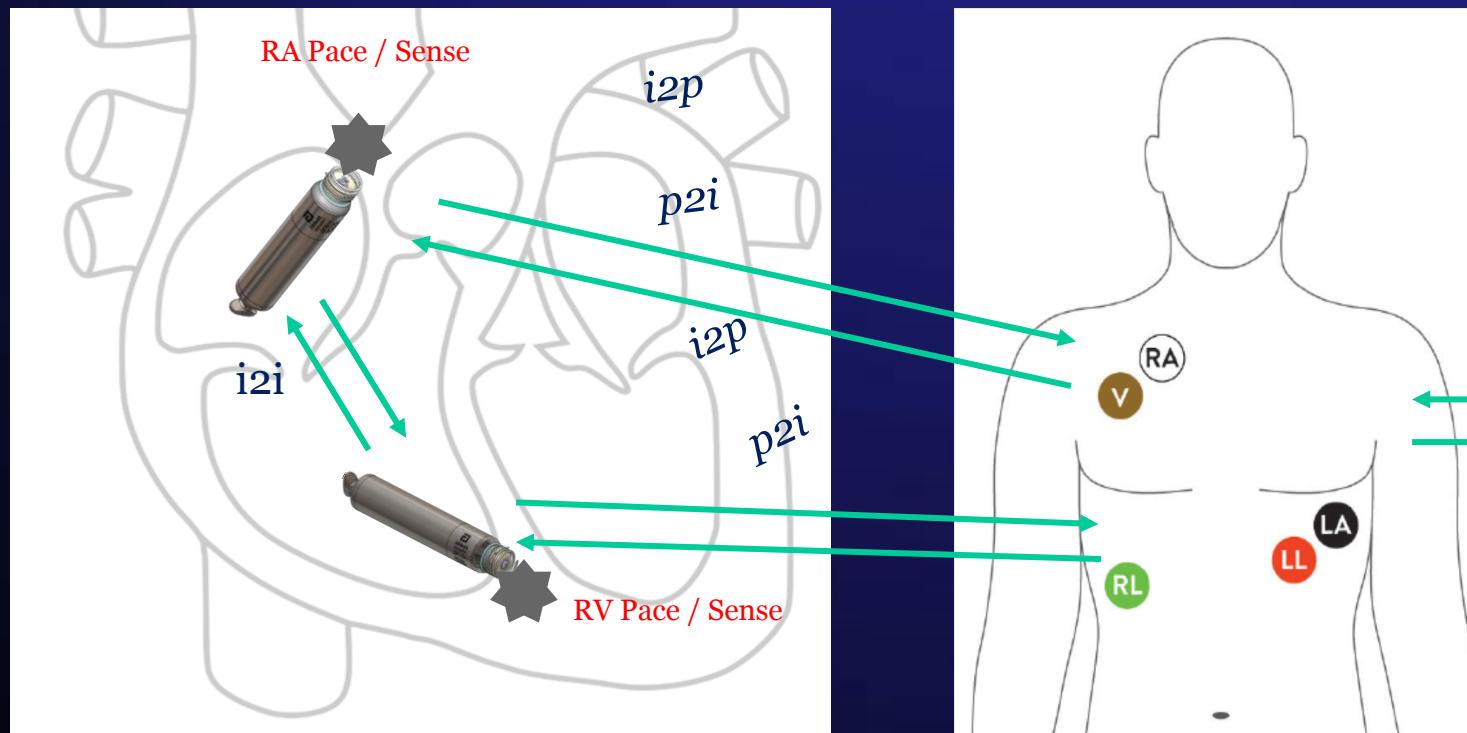
- „High pass“ filtr accelerometer (5-10Hz) – $3 \times \rightarrow 360^\circ$
- Usměrňovací filtr
- Blanking after ventricle activity
- Blanking or increasing threshold post T- wave detection to erase A3 false detection
 - Measurement → hardware
 - Blanking → firmware
- A4 wave detection as the first wave ovecross the filter thresholds
 - Typical 0.10-0.15g



Dvoudutinový leadless Aveir DR

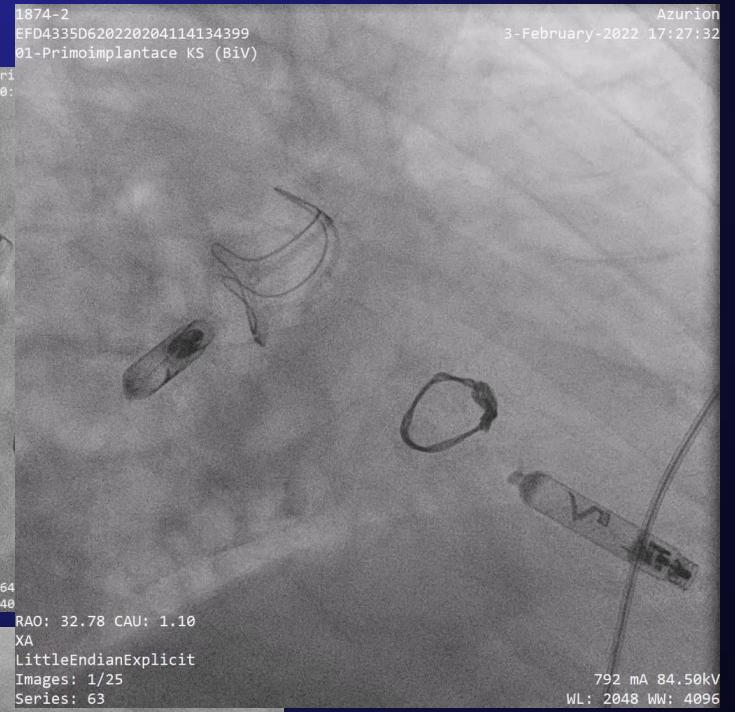
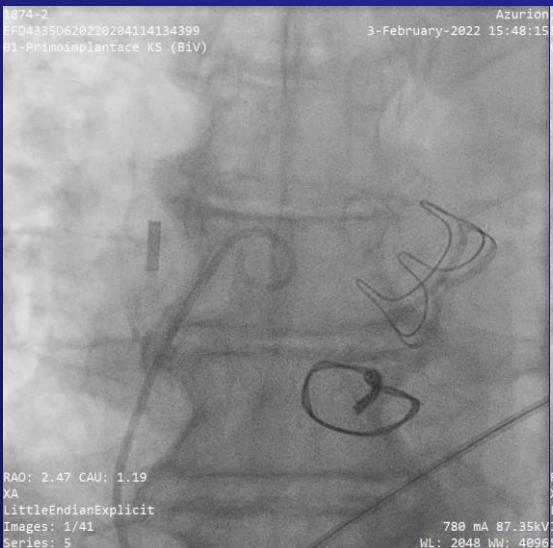
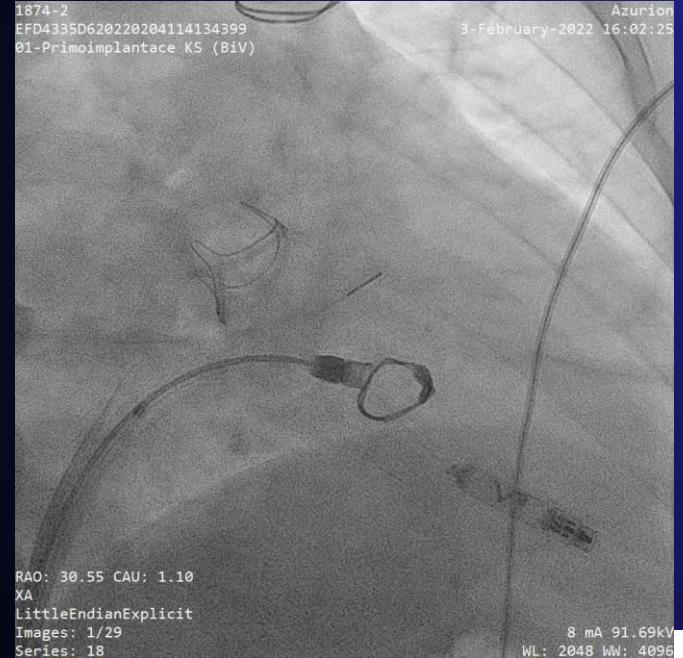
vzájemná komunikace „i2i“ (implant to implant)

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

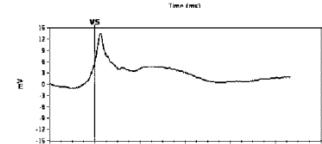
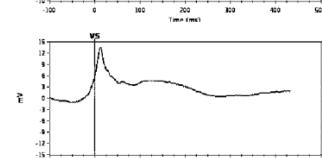
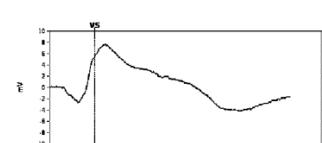


Dvoudutinový leadless Aveir DR

implantace komorové a síňové komponenty

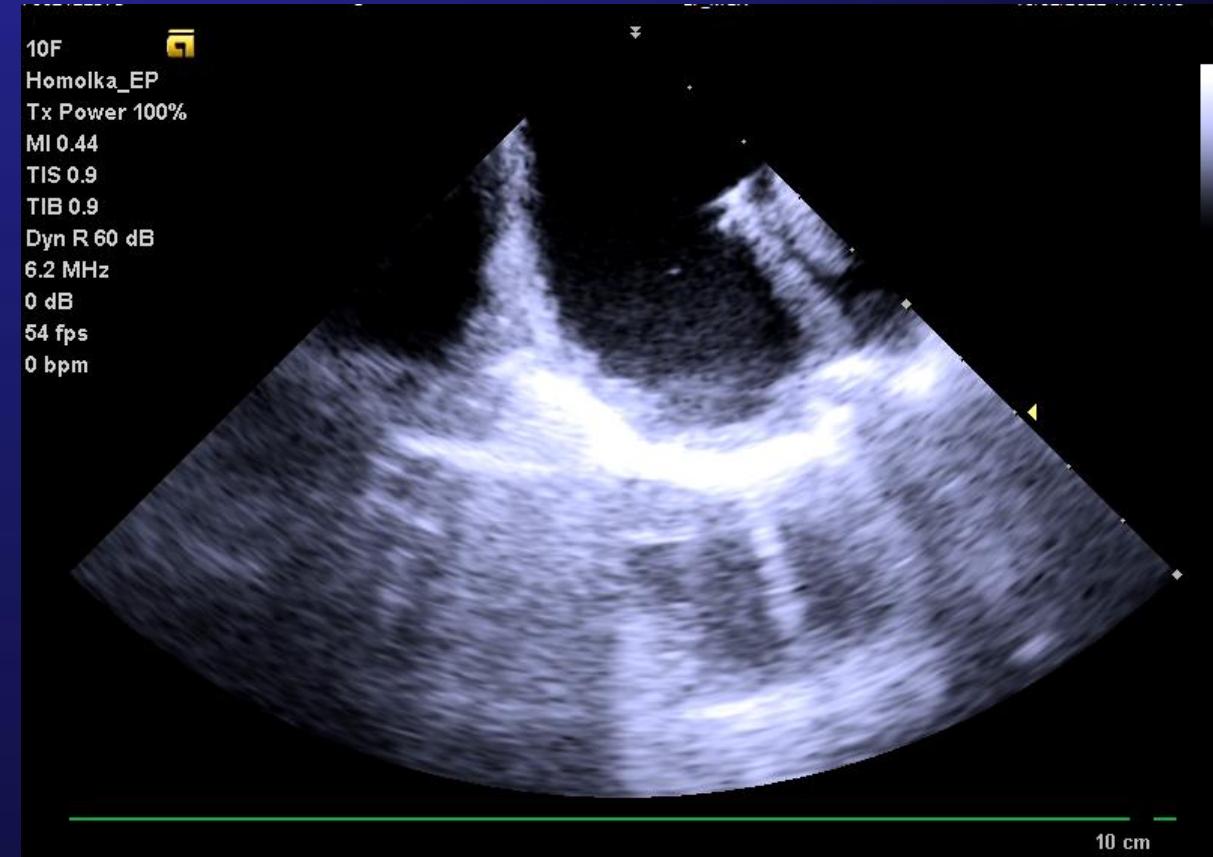
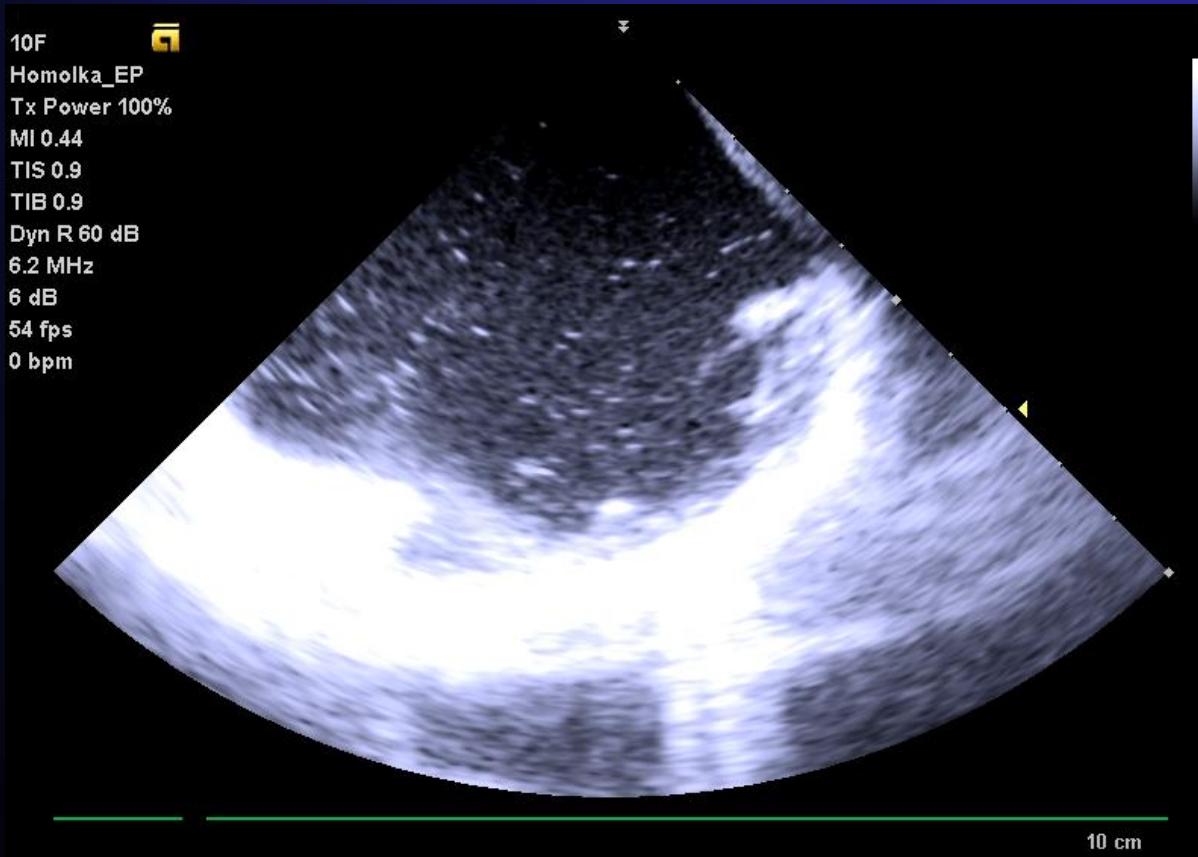


RV CEGM Summary



Dvoudutinový leadless Aveir DR

implantace síňového Aveir - ICE



Leadless pacing & S-ICD

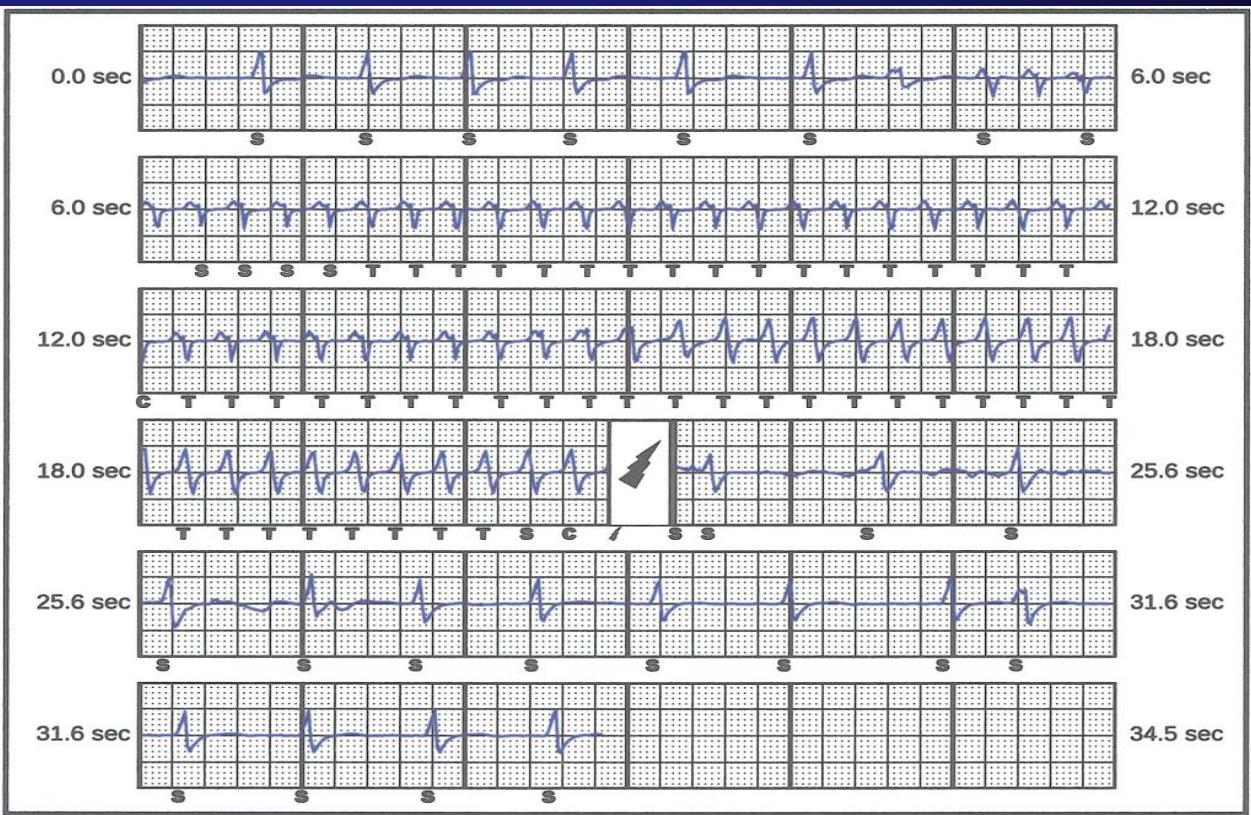
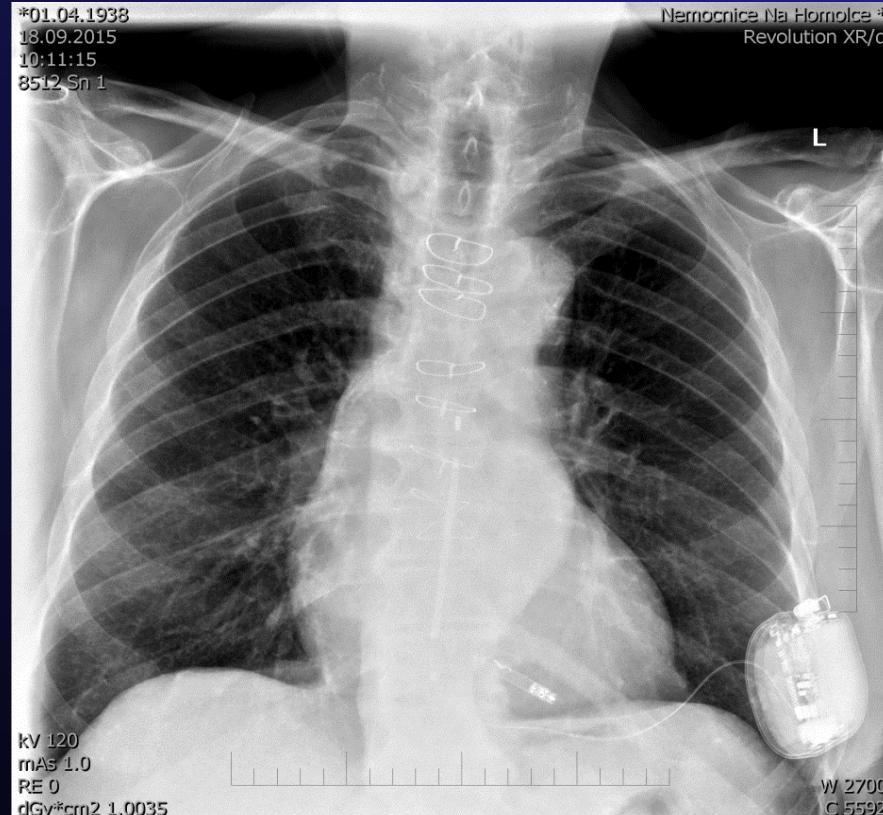
(no inter-device communication)

81 y/o/m

CAD – CABG 2002

Long-standing Persistent AF, LCP implantant 2012

Incessant VT 2014 , LV EF 35%, S-ICD 2015, VT Catheter Ablation 2015



Leadless brady & ATP & S-ICD

Implantable Devices



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

Programmers

Model 3200 S-ICD Programmer



Next Generation
BSC 3300 LATITUDE
Programming System

EMPOWER™ Details

32.1 mm x 6 mm
0.8 cc



Active fixation talons
Tether / Snare port



EMPOWER™ Delivery and Retrieval

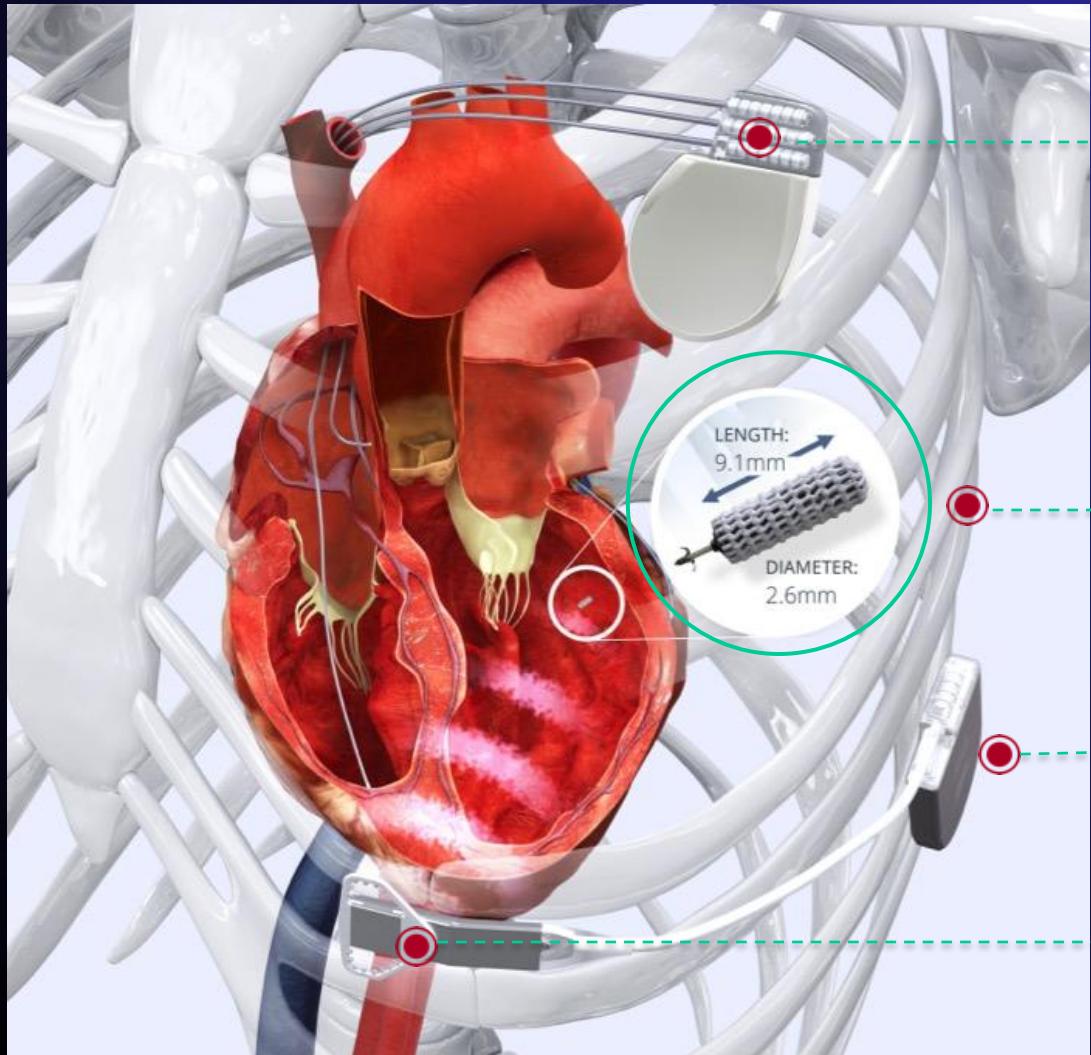
Preloaded delivery
catheter with
extendable inner
catheter



Dedicated delivery and retrieval catheters

WiSE CRT System

Hlavní součásti a princip „wireless“ stimulace



CO-IMPLANT DEVICE

Co-implanted pacemaker, ICD or CRT paces the right ventricle.

RECEIVER ELECTRODE

Implanted onto the endocardium, the receiver electrode converts ultrasound energy into electrical energy to pace the left ventricle.

BATTERY

Implanted subcutaneously on the left mid axillary line, powers the transmitter.

TRANSMITTER

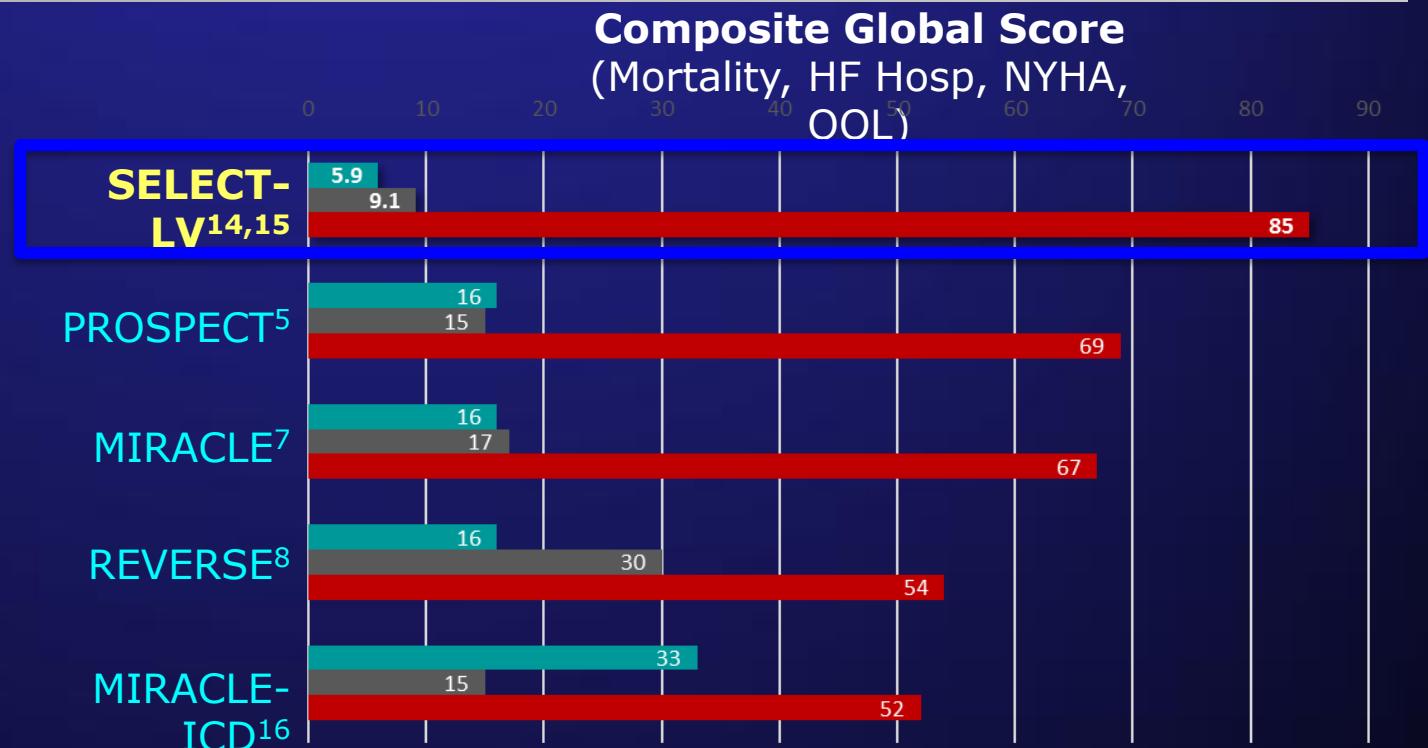
Phased array ultrasound transmitter is implanted sub-muscular over a cardiac echo window. Synchronizes with an RV pacing pulse to transmit ultrasound energy to the receiver electrode to provide Bi-V endocardial pacing.

Studie SELECT-LV : Hlavní výsledky

The SELECT-LV study showed sustained cardiovascular improvement for complex CRT patients treated with the WiSE System

85%
of patients
experienced
persistent clinical
benefits at 6-months

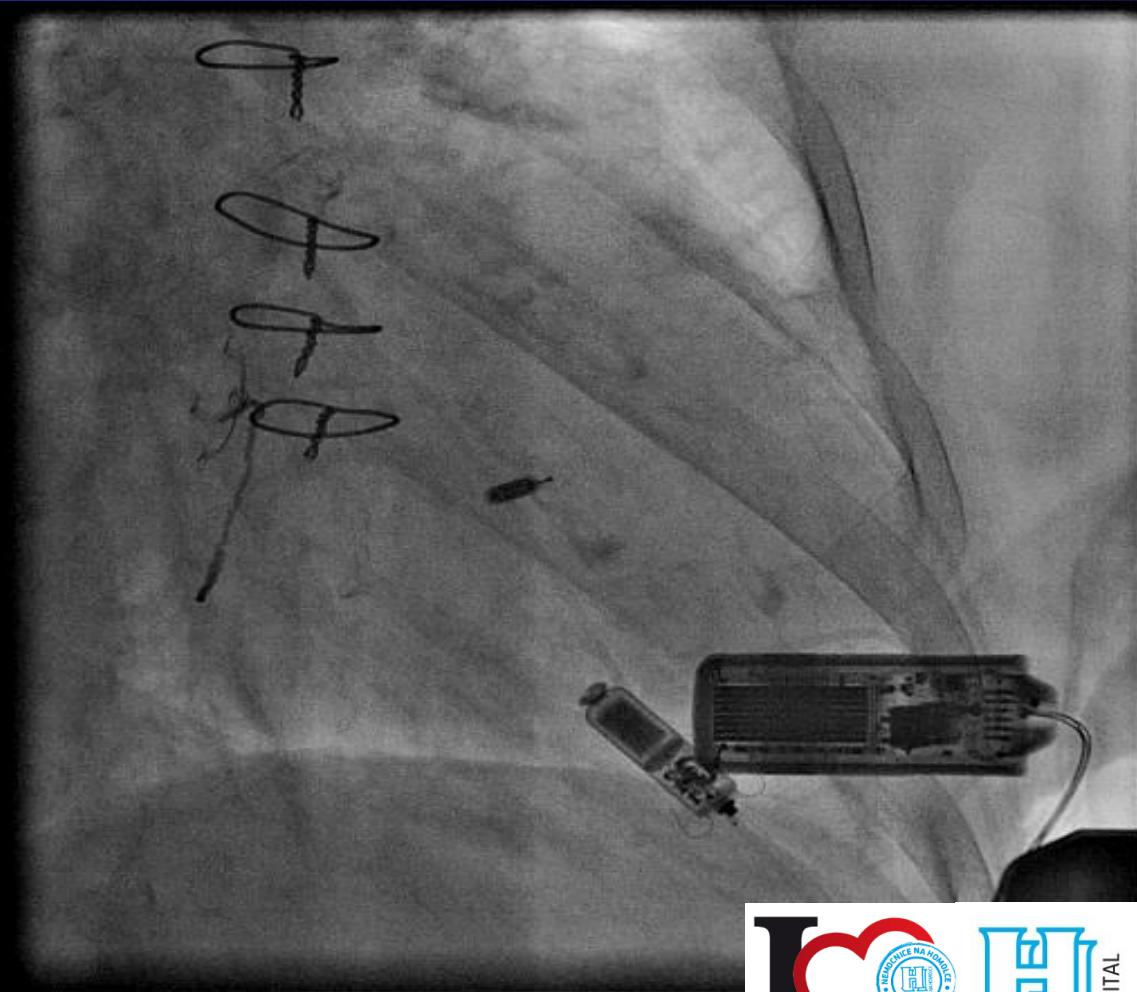
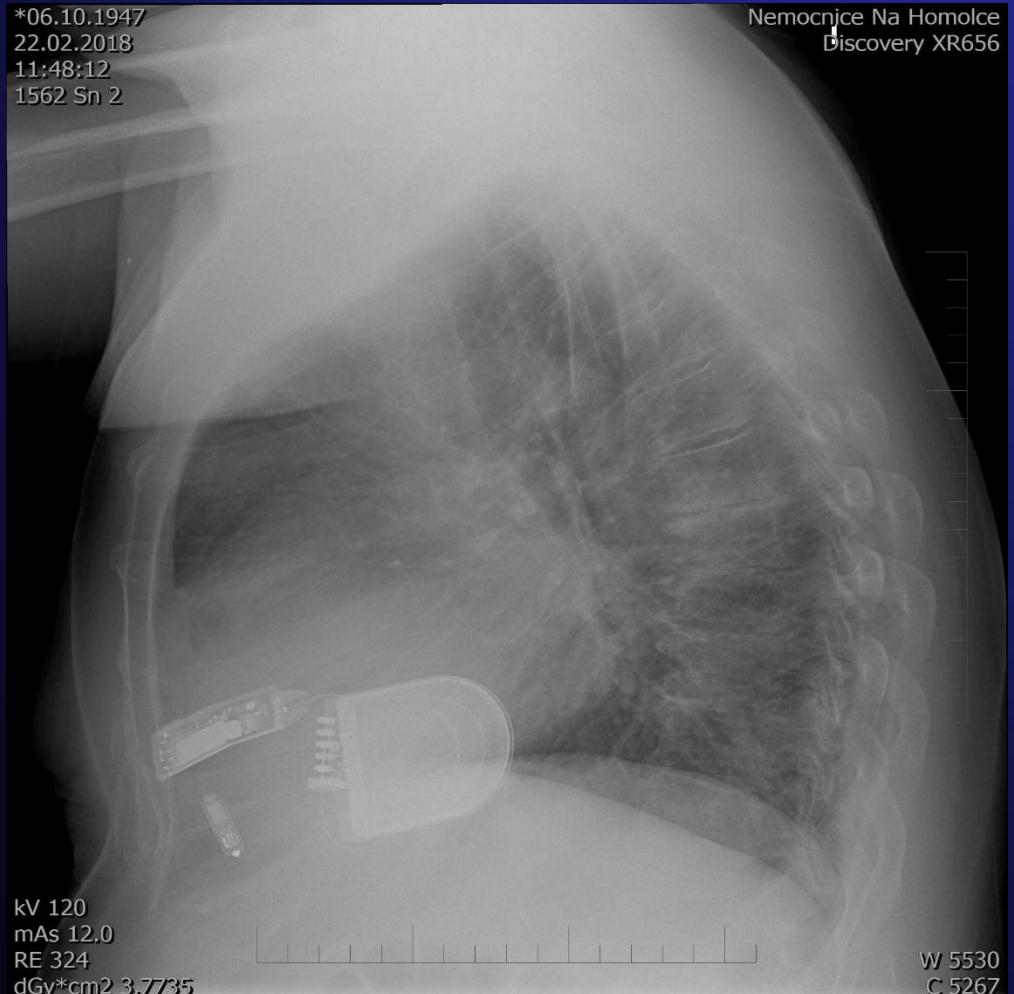
- Worsened
- Unchanged
- Improved



This pts group had previously failed conventional CRT

Kompletní leadles-wireless CRT systém

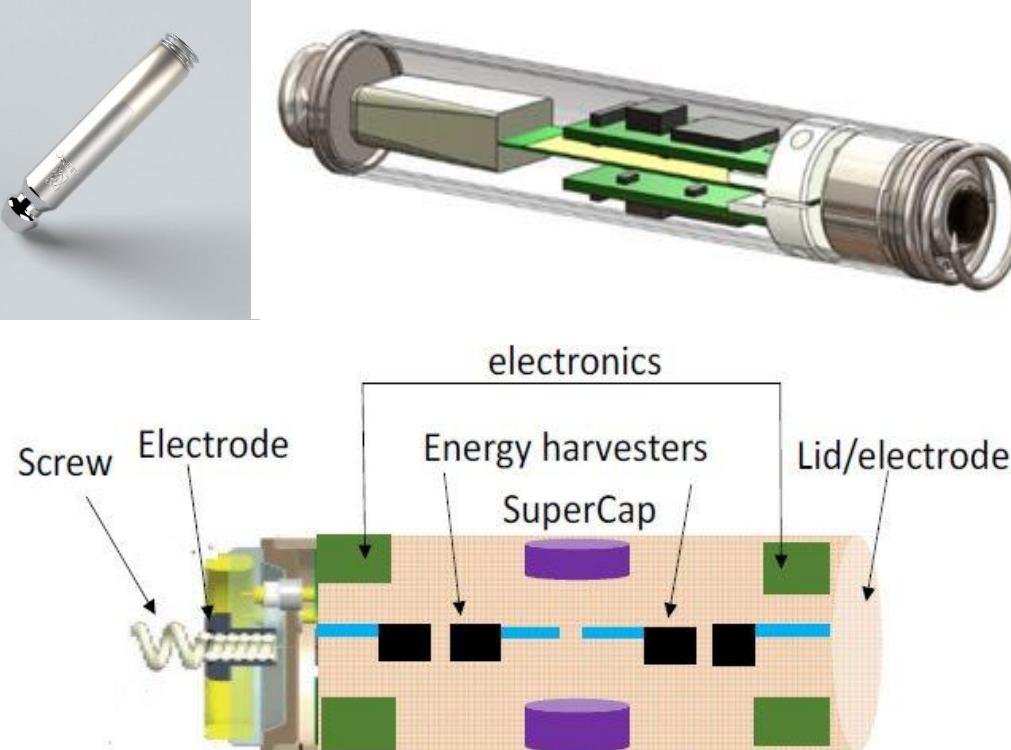
Micra TPS + WiSE



Nová technologie baterií

„harvesting“ energie

- Kardiokinetika jako zdroj energie pro stimulaci:



Parameters	Micra (Medtronic)	ALPS
Polarity	bipolar	bipolar
Pacing modes	VVIR (single-ch)	VVIR / DDDR
Rate modulation	3D accelerometer	3D accelerometer
Energy supply	Lithium iodine battery	Piezoelectric energy harvester
Estimated longevity (ISO)	5 y	> 20y
Size (D x L) mm	6,7 x 26	6,5 x 30
Fixation mechanism	Tines	Helix + torque limiter
Delivery	Femoral catheter access	Femoral catheter access
Other features	Hourly/daily based pacing threshold verification Automatic sensing adaptation Holter episode for EGM + Acceleration	Beat to beat capture verification Automatic sensing adaptation Daily/weekly Home-monitor transmission

Kdy indikovat Leadless kardiostimulátor

- V případě opakovaných infekčních komplikací spojených s transvenózními KS systémy a to i bez ohledu na základní rytmus (FiS/SSS/SR s AVB)
- Implantace LP (*MICRA VVI/AV*) *i v případě probíhajícího septického stavu*
- Implantace LP (*MICRA VVI/AV*) *v případě rizika akutní komplikace subklaviální punkce, okluze SVC či obliterace centrálního žilního systému*
- *Fibrilace síní (LP VVI)* - *vysoce aktivní pacient s rizikem porušení transvenózně zaváděné elektrody chabé podkoží s rizikem vývoje dekubitu trikuspidální plastika či MVR riziko poškození trikuspidální chlopně*

PRAGUE HOMOLKA Hope:

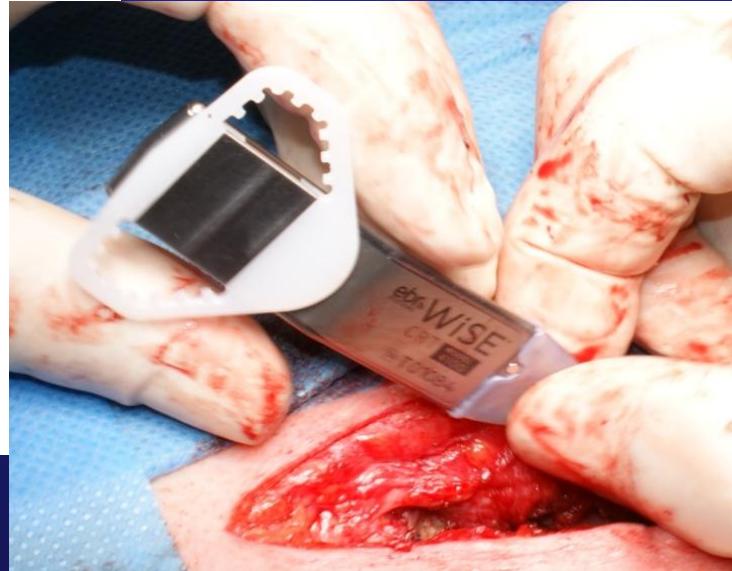
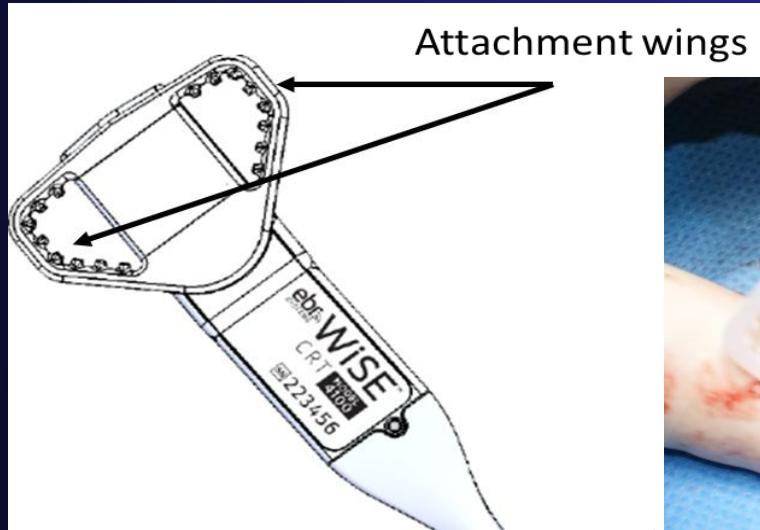
LEADLESS PLATFORM FOR ALL:

COMING SOON

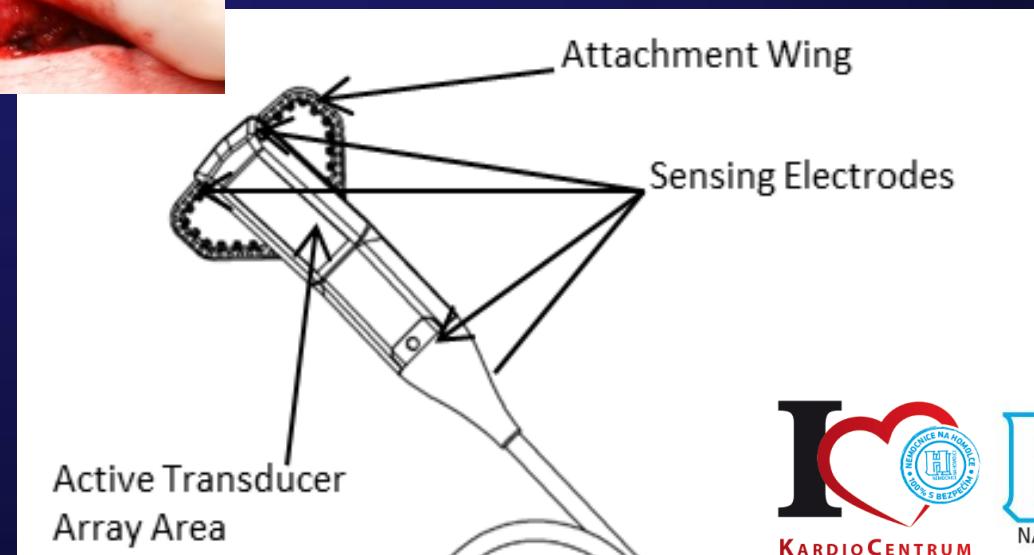


WiSE CRT System

Ultrazvukový transmitter

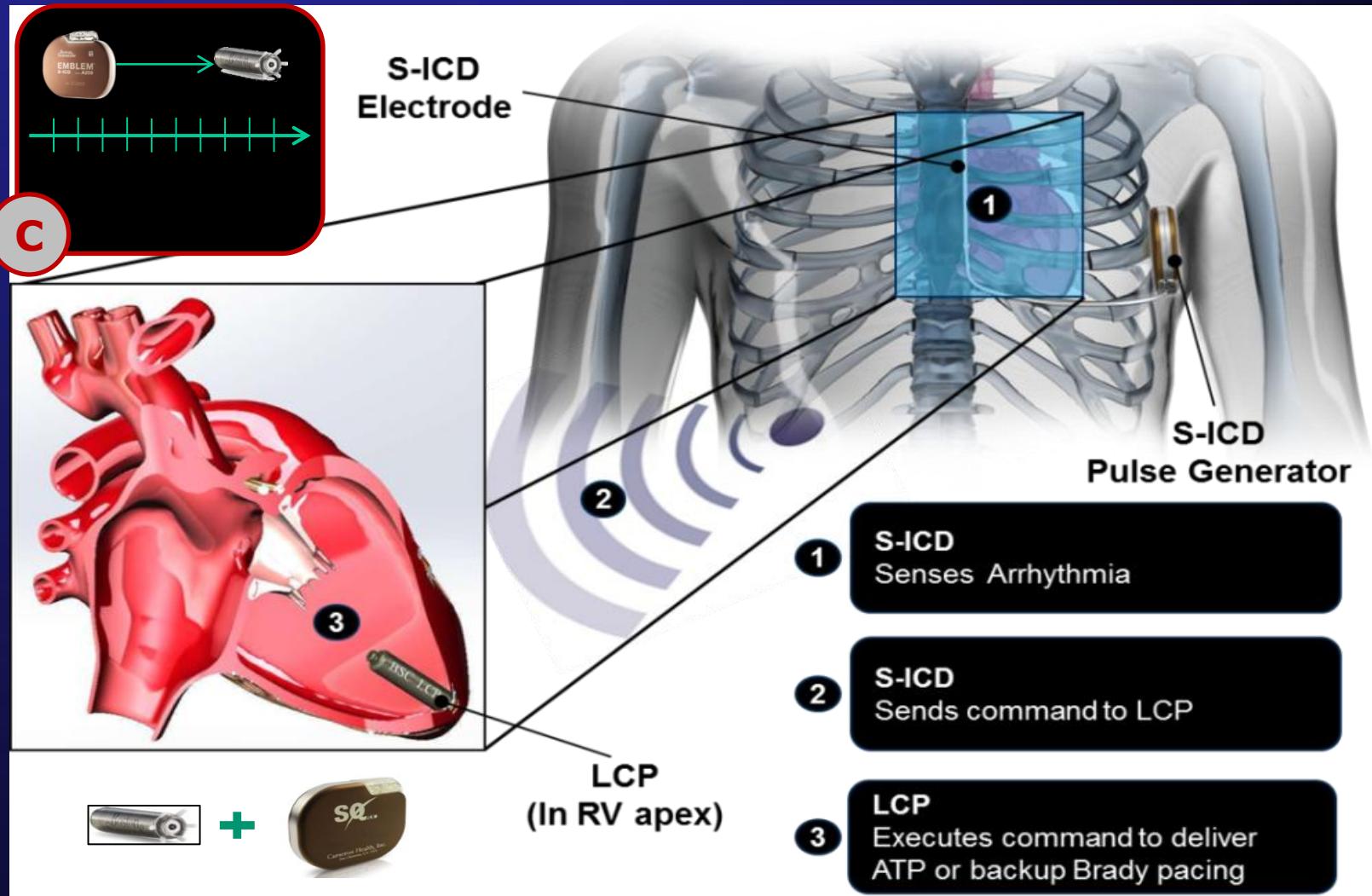
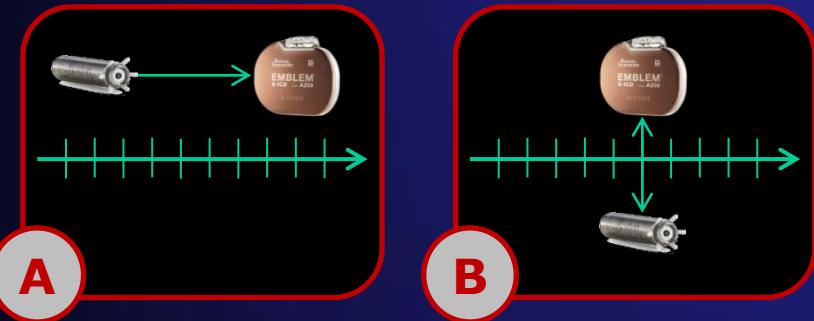


- Detects co-implant RV Pulse
 - Uses sensing electrodes
 - Discriminates RV pulse using pulse-width
 - Compatible with any co-implant / RV lead



- Focuses and Steers Ultrasound Beam
 - Targeted beam improves power transfer efficiency
 - “Find” the RE (typ 3ms, max 10ms)
 - Send Pacing Pulse energy to RE location

Leadless brady & ATP & S-ICD



mCRM™ mechanizmus komunikace : Modular

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

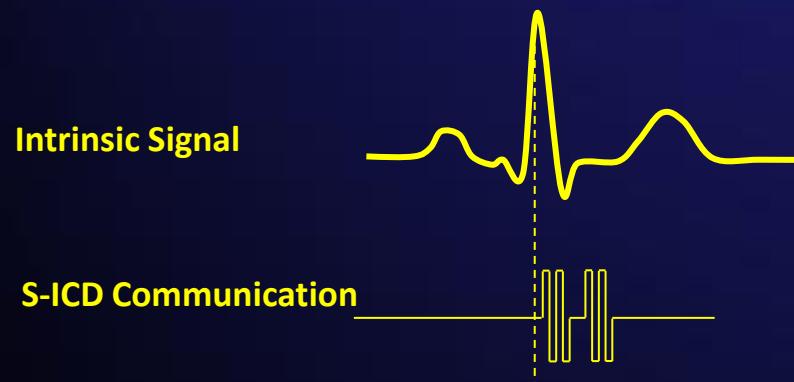
- Insight Algorithms with SMART Pass technology
- Up to 3 attempts of ATP in Conditional Zone
- QuickConvert in the Shock Zone

mCRM Compatibility

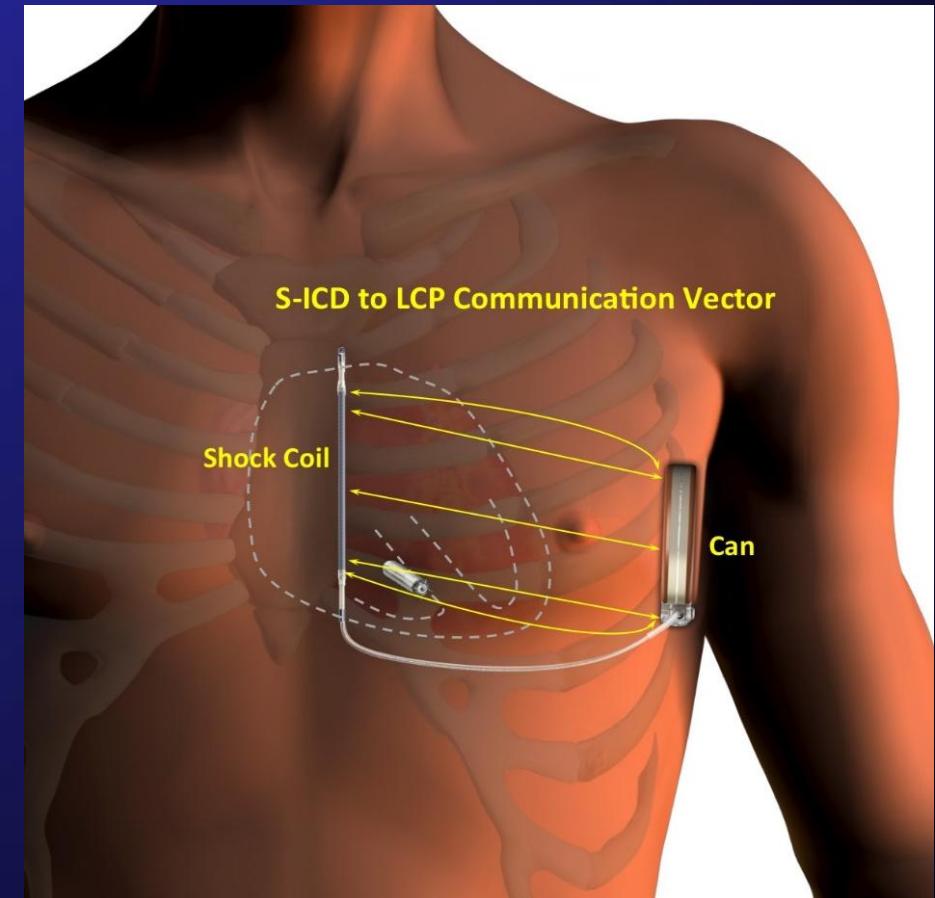
- EMPOWER™ MPS is designed so that all EMBLEM™ S-ICDs are capable of mCRM™ upgrade to benefit from modular therapy and TruATP™

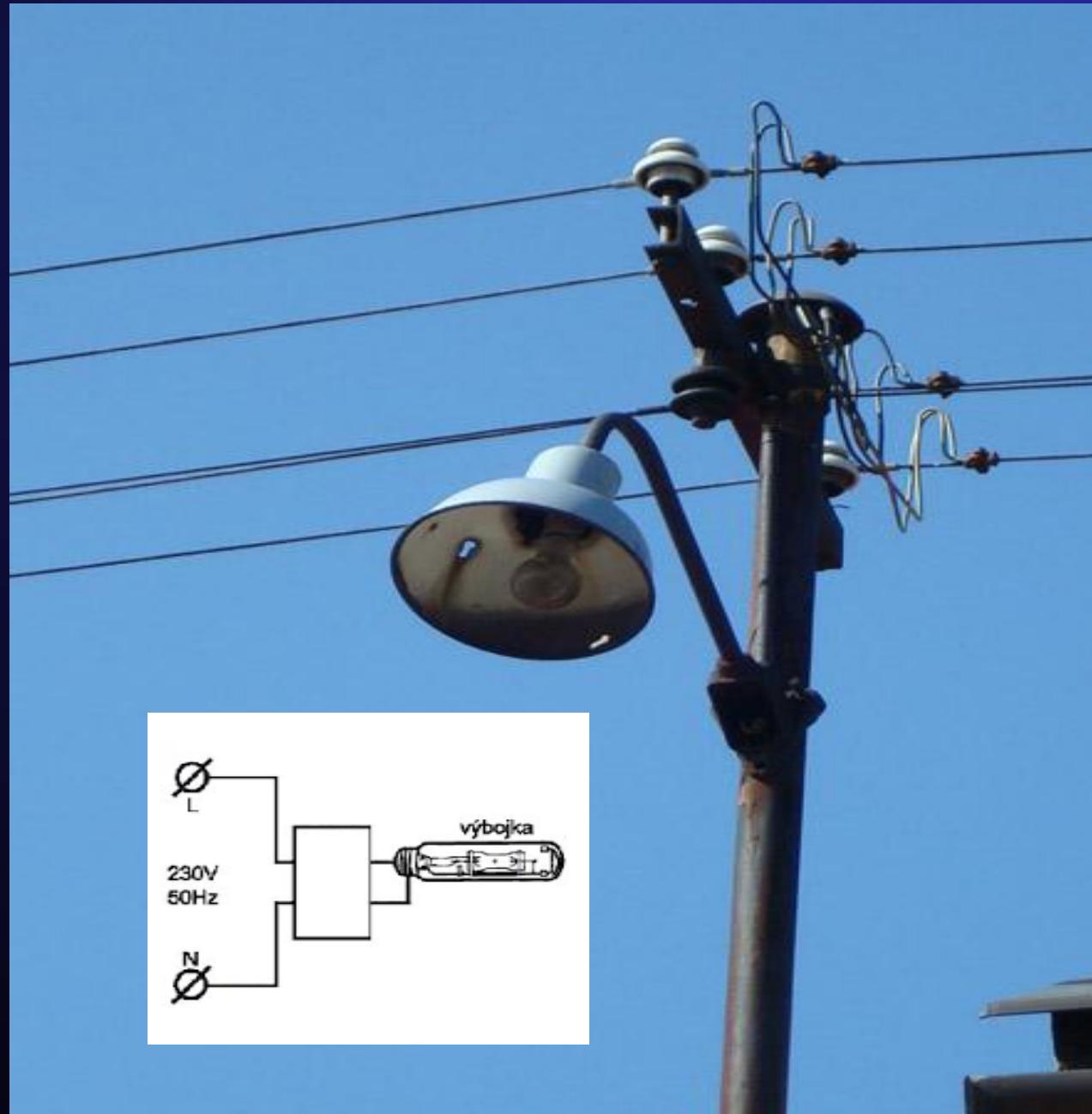
mCRM™ Communication

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



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





Nanostim Leadless dvoudutinová stimulace

Nový systém AVEIR™ — Implantace In-Vivo

AVEIR™ IMPLANTAČNÍ & EXTRAKČNÍ SYSTÉM



AVEIR™ Leadless STIMULÁTOR



AVEIR™ KOMUNIKACE MERLIN PCS



Get PDF Document
Get Document Manager Info
Get Software Update
Merlin™ PCS

Vzájemná komunikace - i2i (“implant to implant”)

- i2i komunikace se zahajuje každou elektrickou srdeční aktivitou

i2i communication repeats for **every cardiac event**

- Atrial to ventricular (A2V)
- Ventricular to atrial (V2A)

Occurs immediately before paced or following sensed event

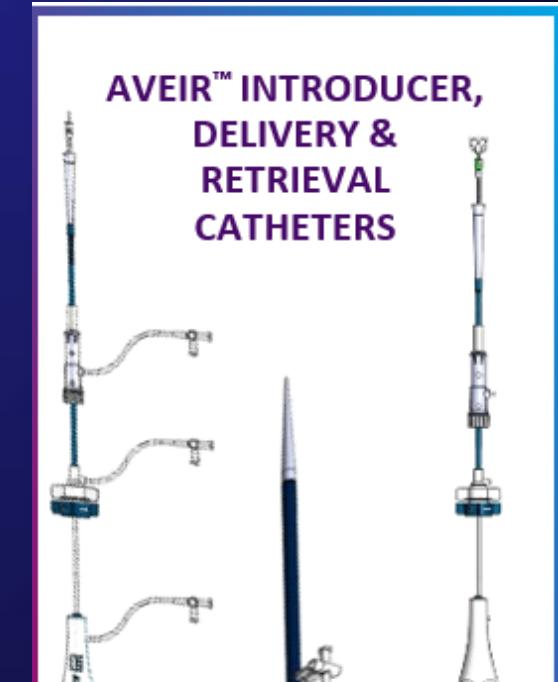
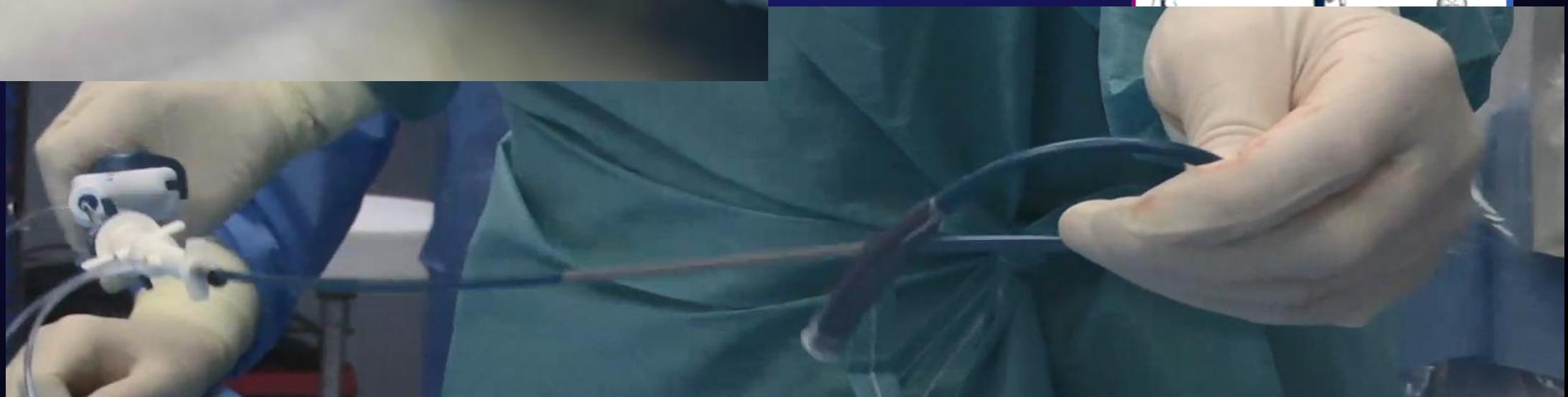
Example: A to V i2i prior to Ap

Example: V to A i2i after to Vs

The diagram shows a simplified line drawing of a human heart. Two pacemakers are implanted within the chambers. The top one is labeled 'A2V' and the bottom one 'V2A'. Blue curved arrows originate from each pacemaker and point towards the opposite chamber, illustrating the bidirectional communication (i2i) between the atria and ventricles.

Dvoudutinový leadless Aveir DR

zavaděcí katetr



Soubor pacientů (1. implantace 3.2.2022)

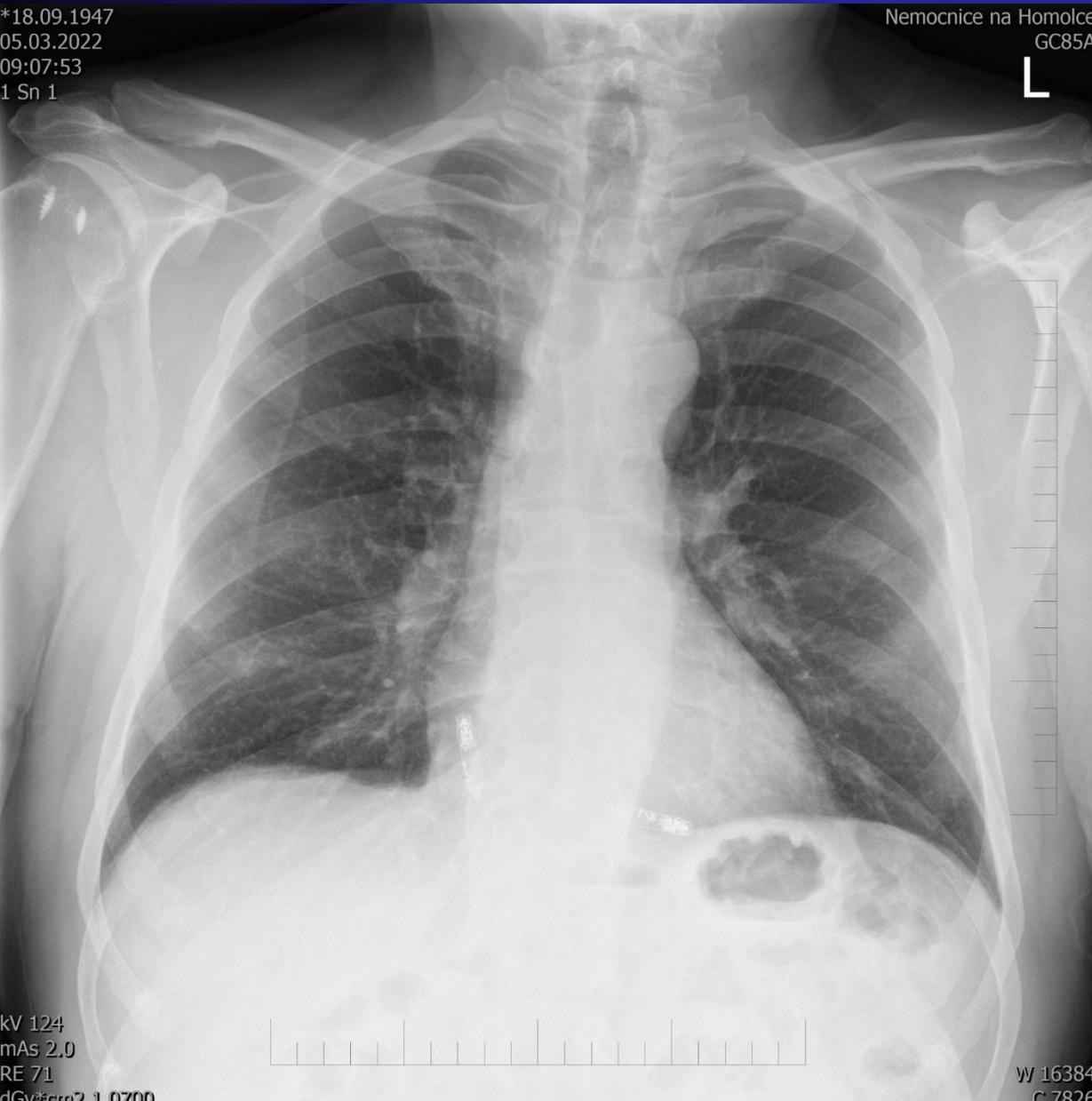
n	17
pohlaví	12 mužů/ 5 žen
Ø věk (roky)	70,3 (35–83)
Indikace SSS/AV blok	8/9
BMI	29,1 ± 4,1

- analgosedace
- femorální přístup
- skiaskopická kontrola + ICE

*18.09.1947
05.03.2022
09:07:53
1 Sn 1

Nemocnice na Homolce
GC85A

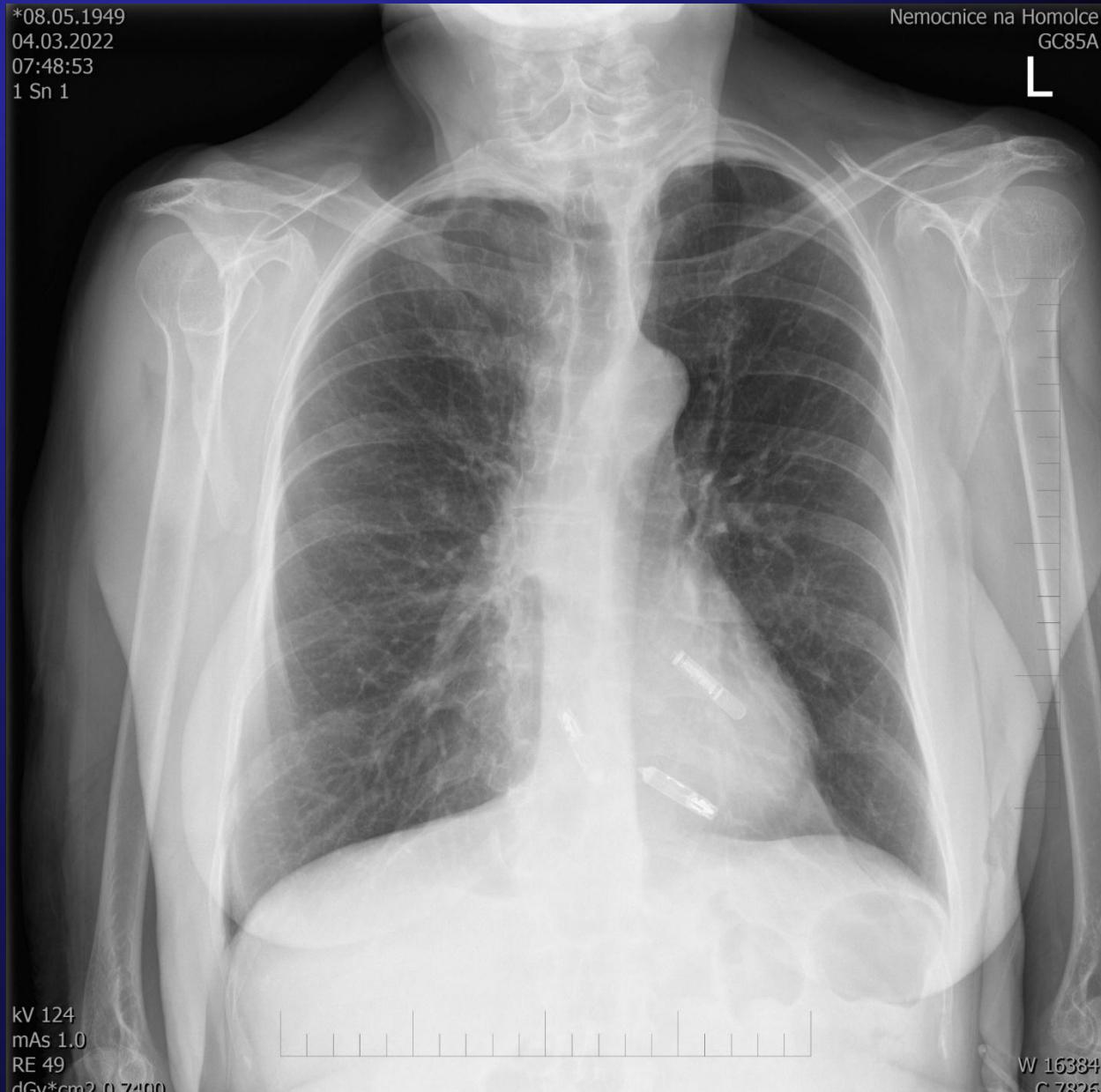
L



*08.05.1949
04.03.2022
07:48:53
1 Sn 1

Nemocnice na Homolce
GC85A

L



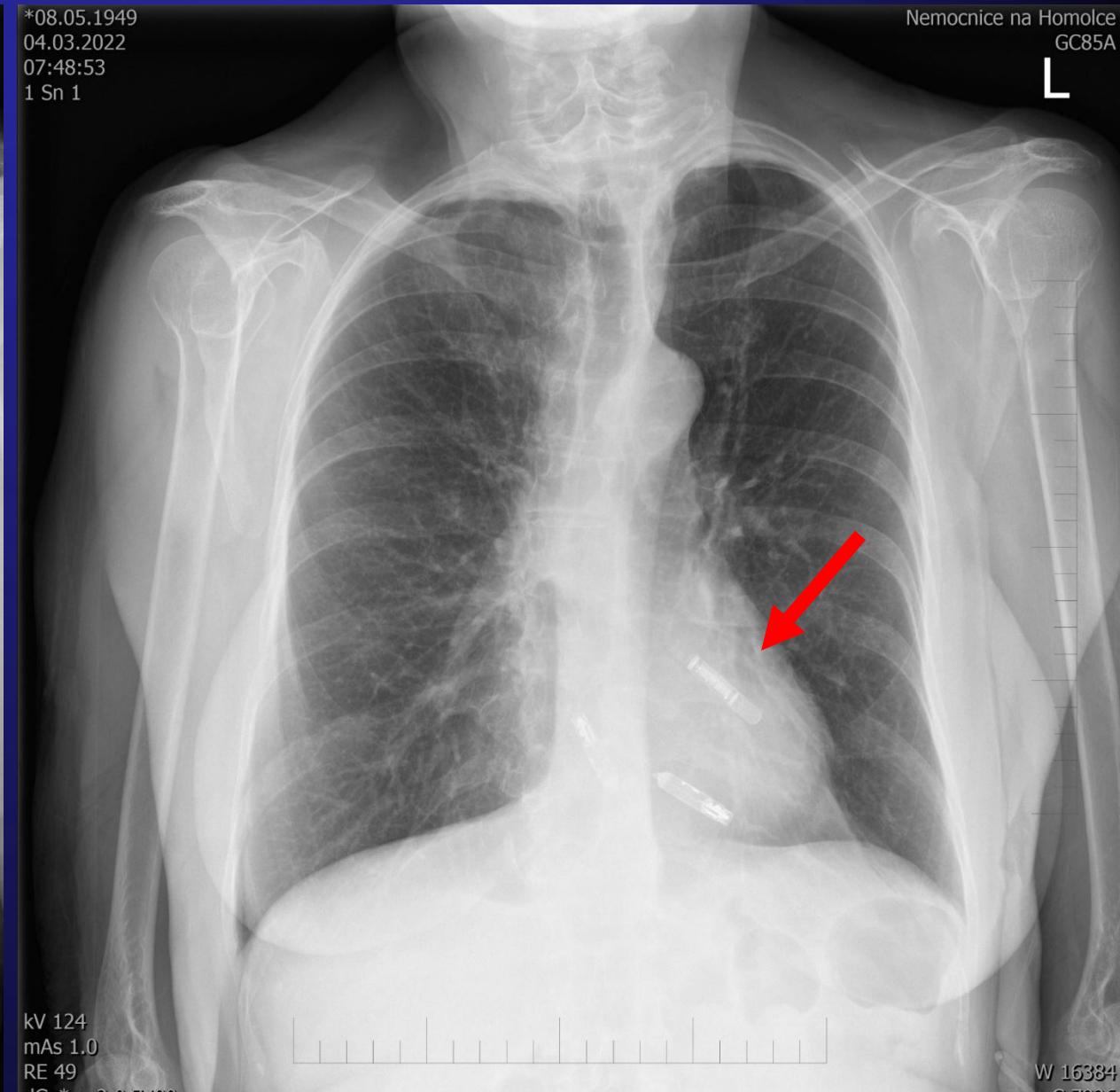
*18.09.1947
05.03.2022
09:07:53
1 Sn 1

Nemocnice na Homolce
GC85A
L

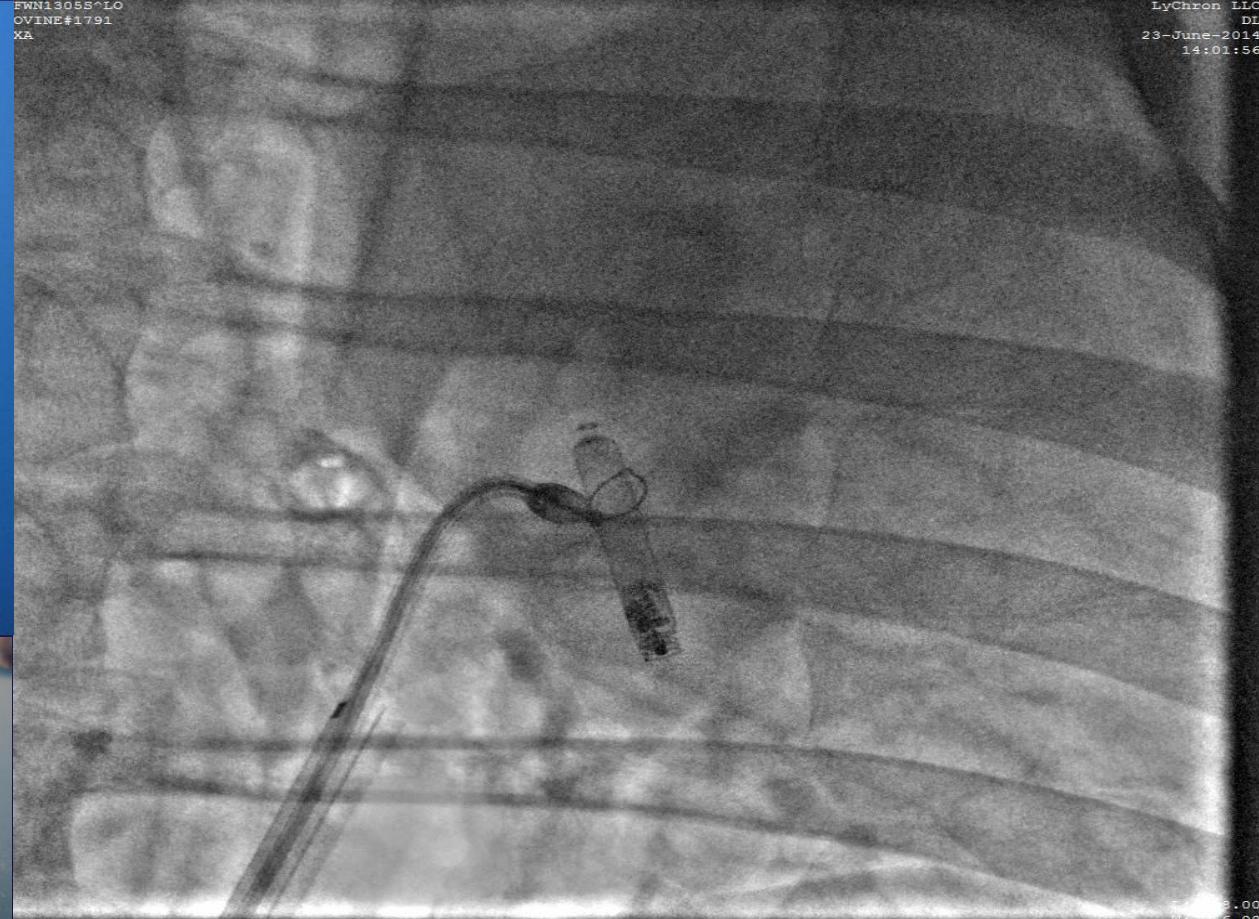
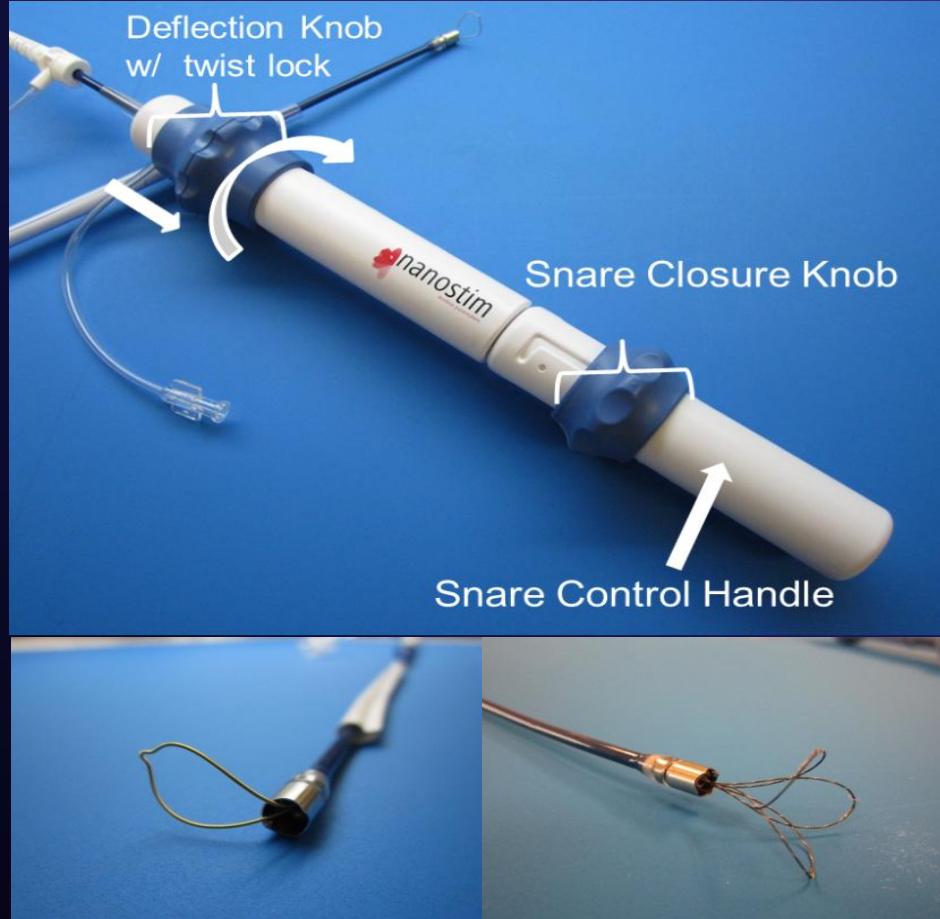


*08.05.1949
04.03.2022
07:48:53
1 Sn 1

Nemocnice na Homolce
GC85A
L

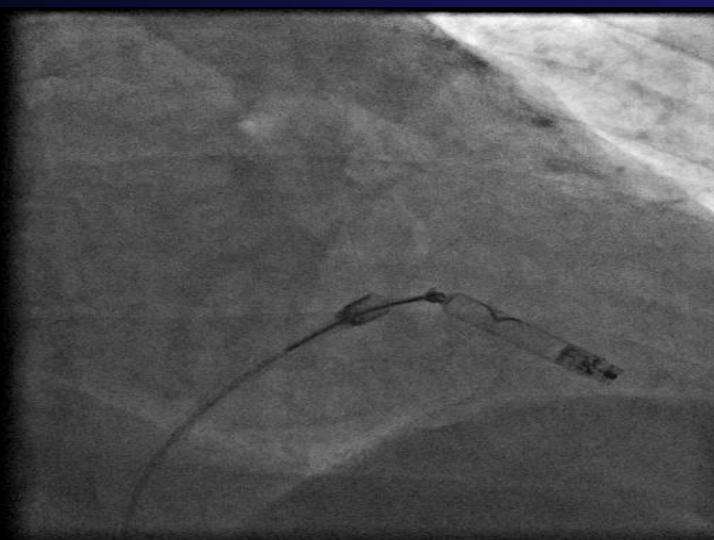
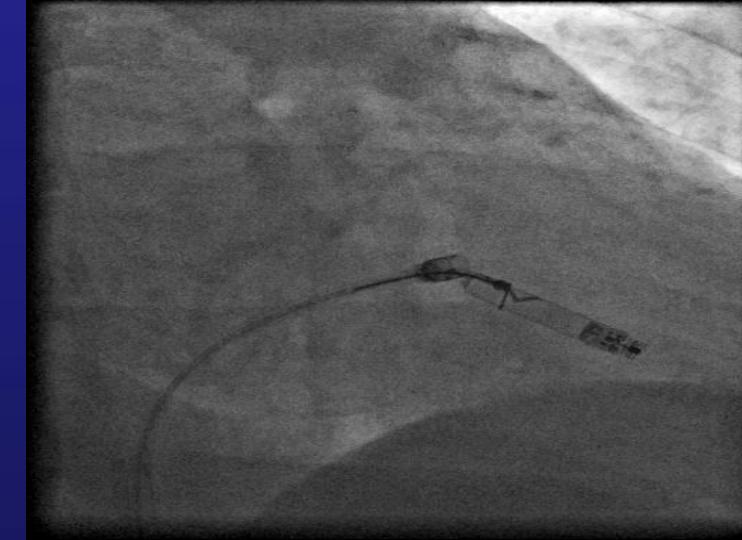
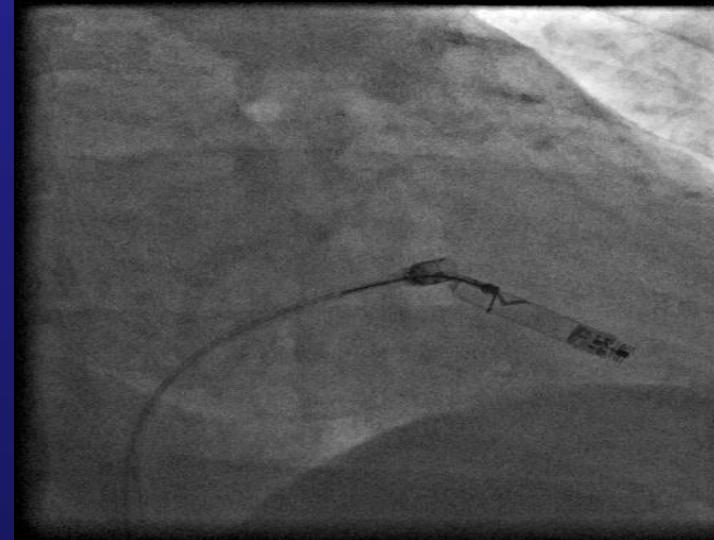
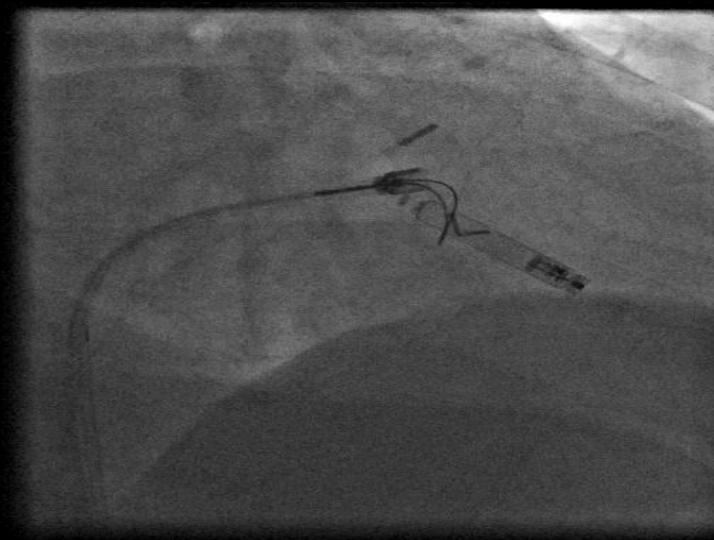


Retrieval Device for Nanostim LCP

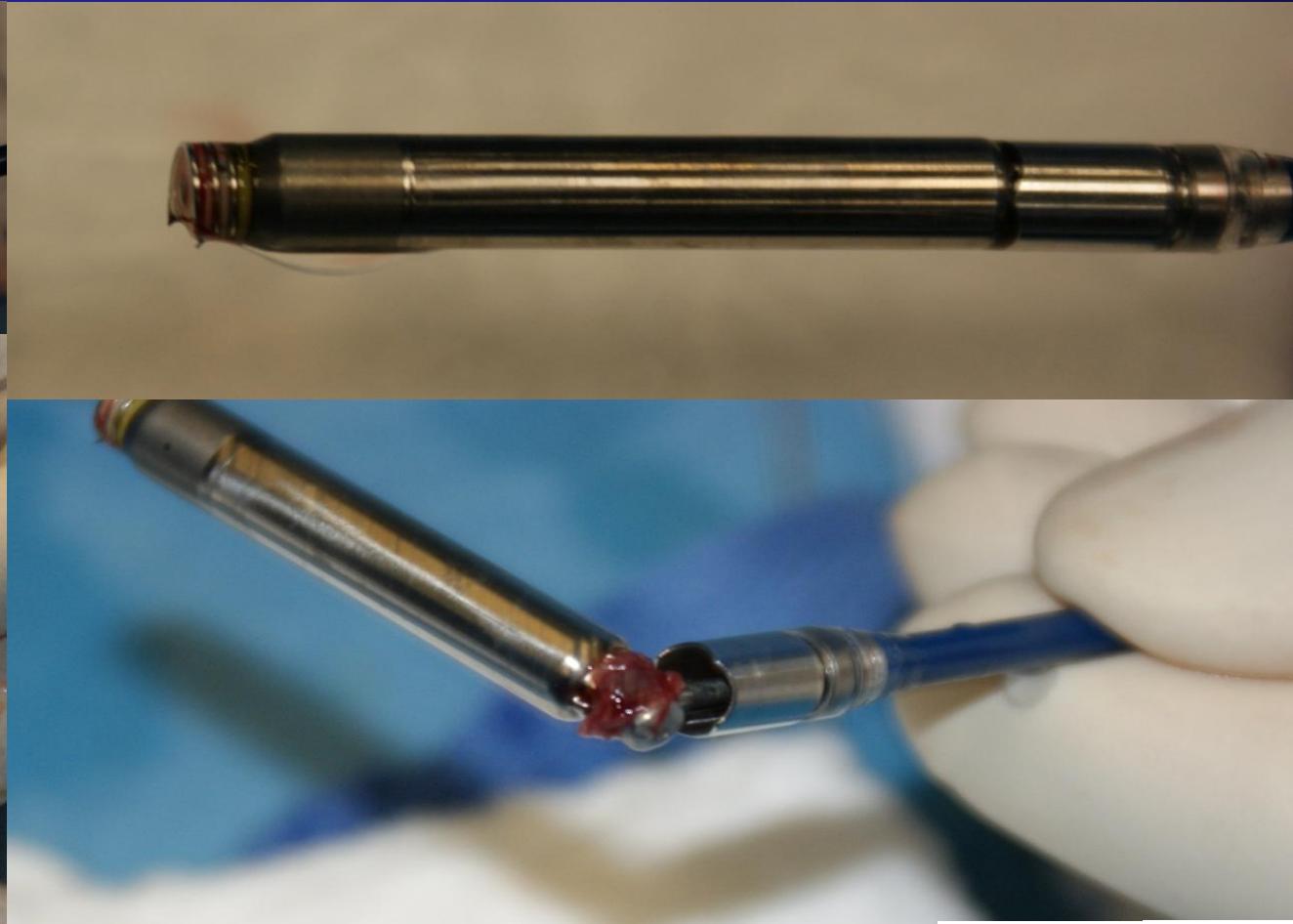
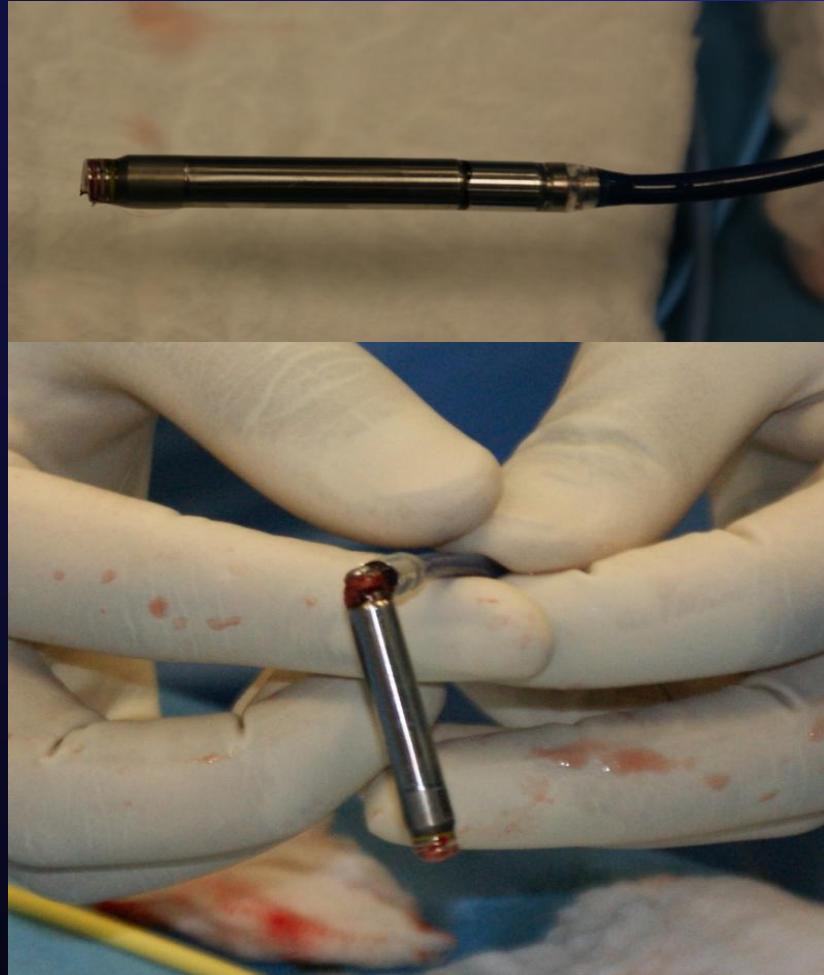


Sperzel J, et al *Europace*. 2013; 15(Suppl 2):860.

Retrieval Nanostim LCP 6 years after First Implant



Retrieval Nanostim LCP: Device Inspection



Retrieval MICRA TPS 1 year + 30 days after First Implant



Retrieval MICRA TPS 1 year + 30 days after First Implant



Retrieval MICRA TPS 1 year + 30 days after First Implant

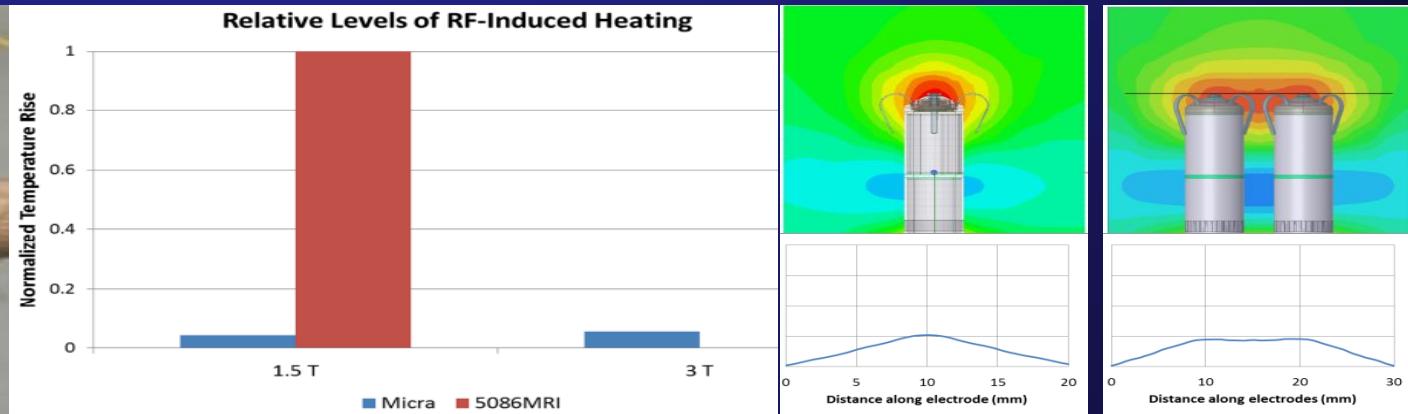


Micra after retrieval:

- A) In the cup of the delivery catheter
- B) Free with talons out with thin tissue layer on the device

Micra TPS : MRI expose

5086 MRI: 2 W/kg, Micra 4 W/kg Phantom: Temperaturfe increase < 0.4 °C
v 99% 1.5T and 3T



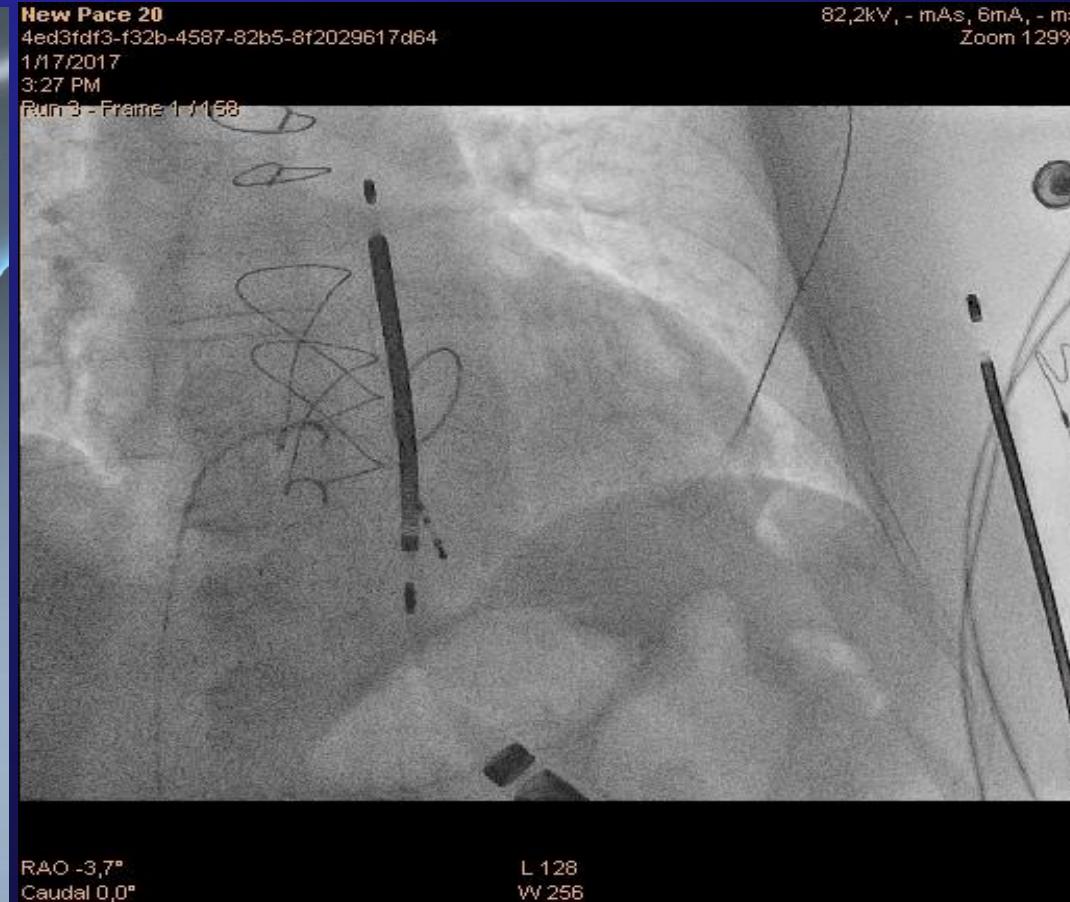
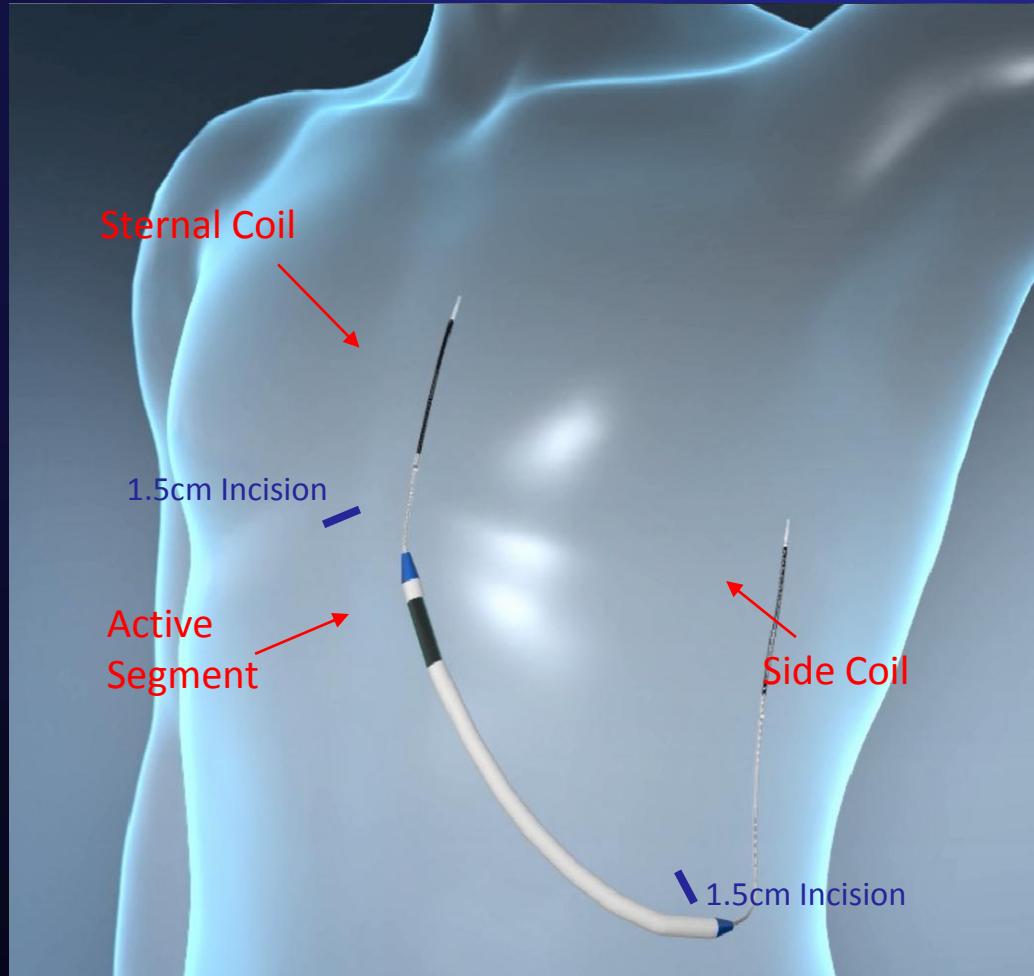
Nanostim & Micra Retrieval: Homolka Experiences

- (NANOSTIM) 68/77 successful retrieval (90.4%)
- Retrieval Failed = 9
 - LP „docking button“ not reached/fracture = 6
 - Detachment of docking button = 3
- Retrieval Success
 - Since Implant: < 1 y: 86%; 1-2 yrs: 93%; >2 yrs: 90%
- Homolka data
 - Nanostim: 37 (29 preliminary battery failure) 21 M/12 W (2 - 7 years)
33 (89%) successful retrieval !!!
 - Micra: 6 (2 battery preliminary discharged) 4M/2W (7 months - 2 yrs)
5 (83%) successful retrieval !!!

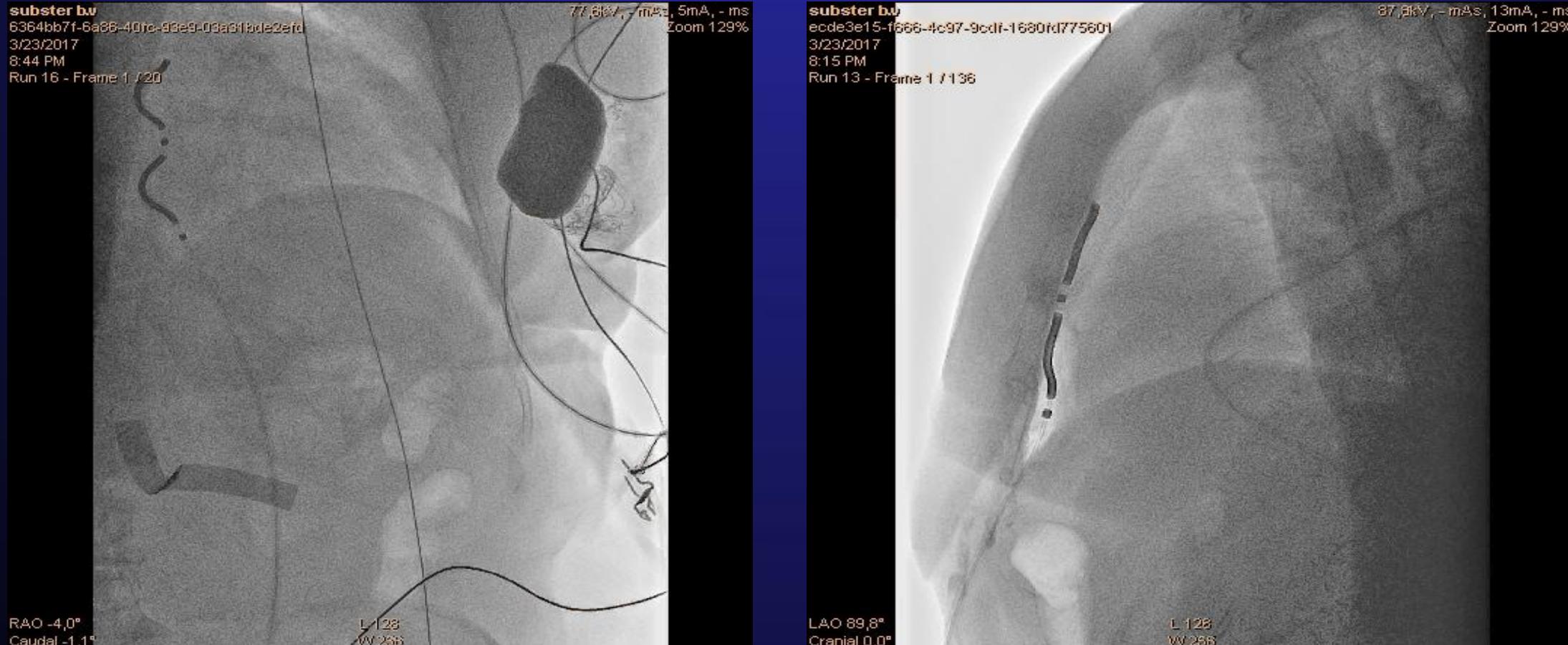


Implantable Subcutaneous String Defibrillator (ISSD)

Basic Concept



Pacing and Defibrillation Performance of Mediastinal vs Subcutaneous Electrodes: ASD 2 Trial



Study demonstrated the ability to pace, sense, and defibrillate using a lead designed specifically for the substernal space.

Boersma LVA, Merkely B, Neuzil P et al: JACC EP 2019;2:186

Leadless dvoudutinová stimulace

Nový systém AVEIR™

Changes to the LP docking button from “Flexible Cables” to “Fixed Post”

Updated battery chemistry tested to 72°C confirming chemistry stability

Changes to the LP length :

42.3 mm to 38.0 mm

& diameter from: **18F to 19.5F**

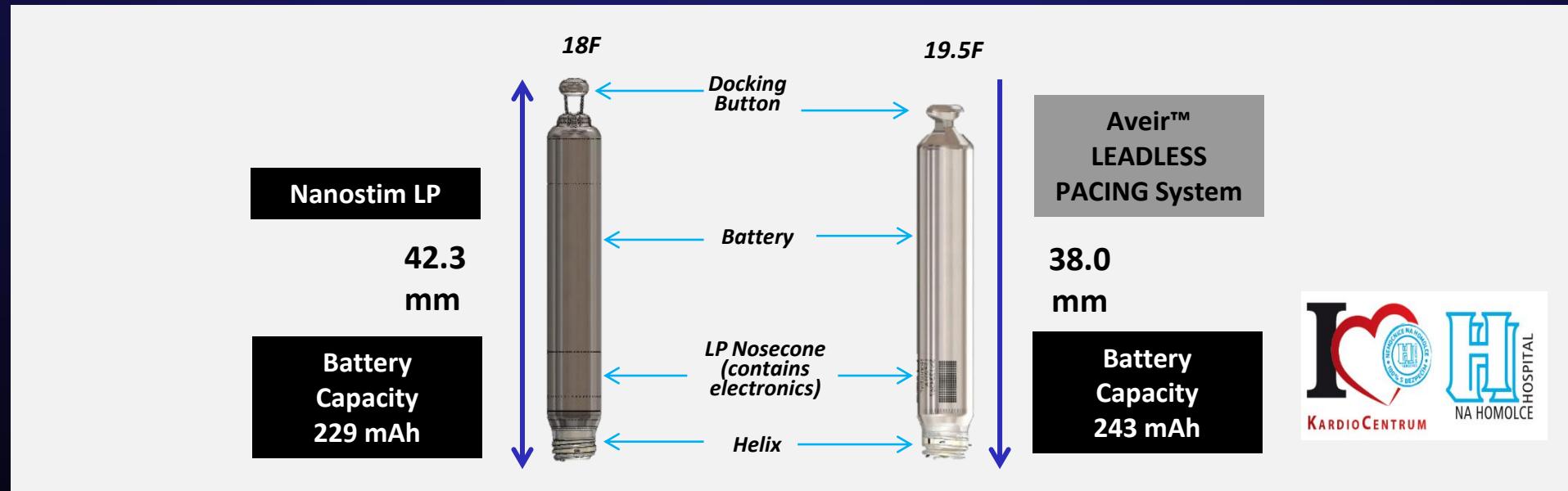
Updates to the LP electronic components while preserving the functionality of the device

Changes to the LP helix to provide additional mitigation to the risk of perforation and helix damage occurring during implant, repositioning or retrieval.

Increased battery capacity: 229 to 243 mAh

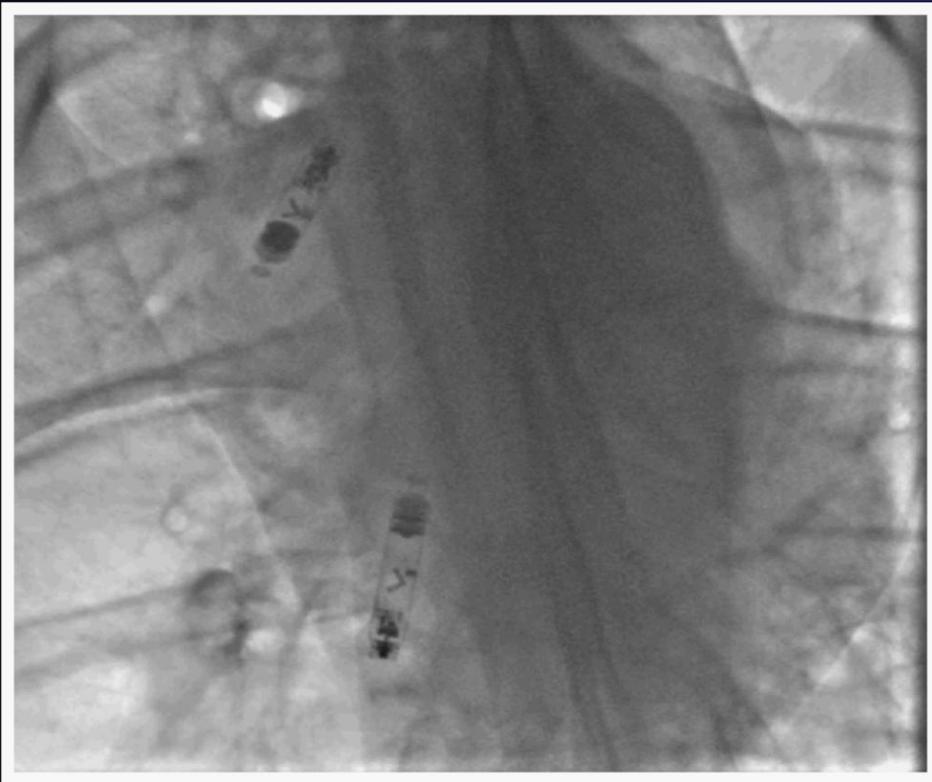
Loadable catheter

Upgradeable to DR*



Dvoudutinová „leadless“ technologie

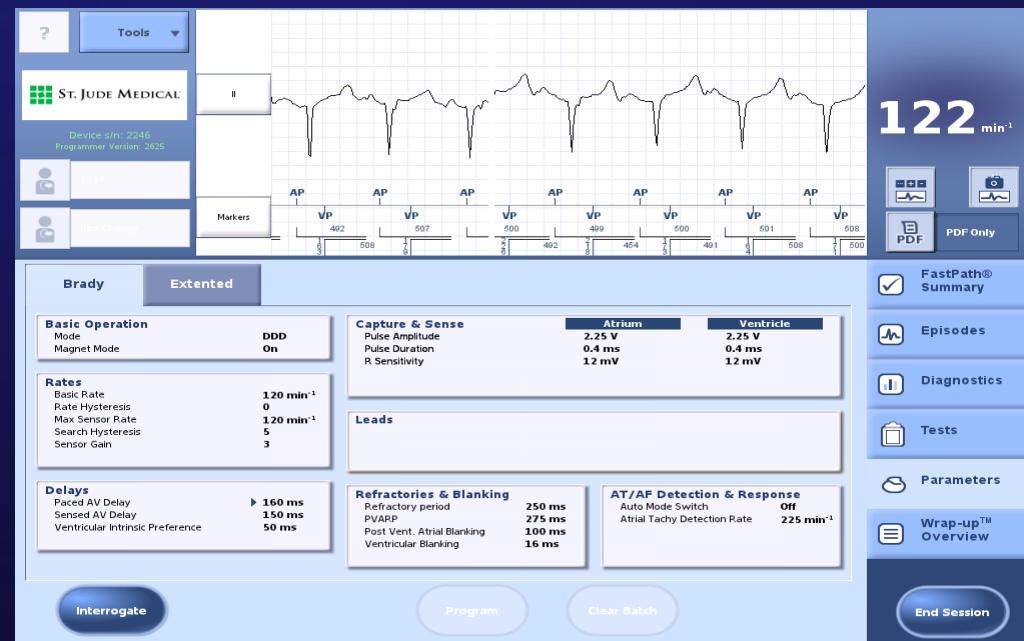
AP



Preklinická implantace DDDR

Develop leadless dual chamber pacemakers that:

- Can be safely implanted into the RA and RV*
- Beat-to-beat communication with an AV delay*
- Provide dual chamber functionality DDD(R) PM*
- Retrievable and upgradeable*



Kazuistika

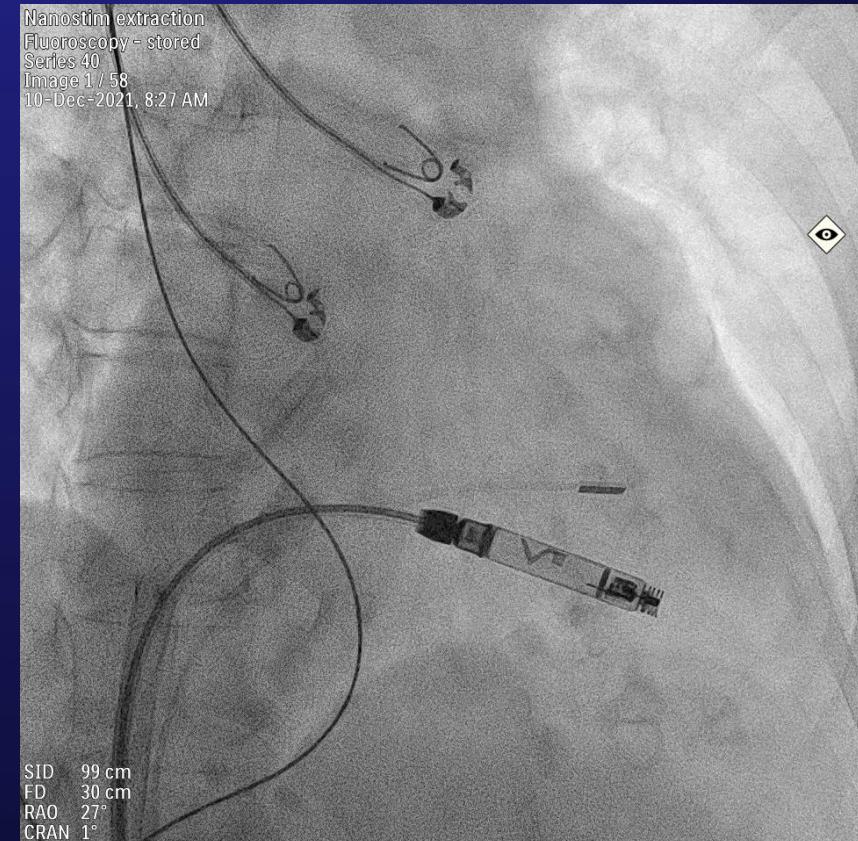
Aveir VR Implantace 12/2021

**Positioning new
AVEIR VR Dec 10, 08:26**



**Aveir VR:
We tried to get
different position
with new LP**

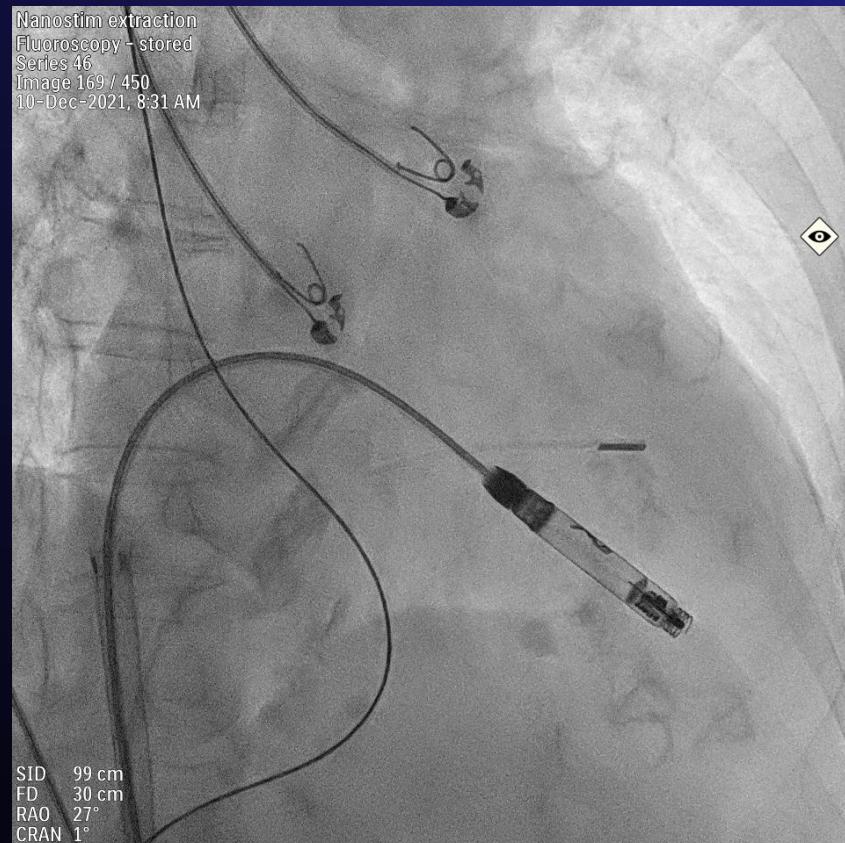
**Re-positioning new
AVEIR VR Dec 10, 08:27**



Kazuistika

Aveir VR Implantace 12/2021

Fixation by slow rotation
AVEIR VR Dec 10, 08:31



Aveir VR:
Easy to implant

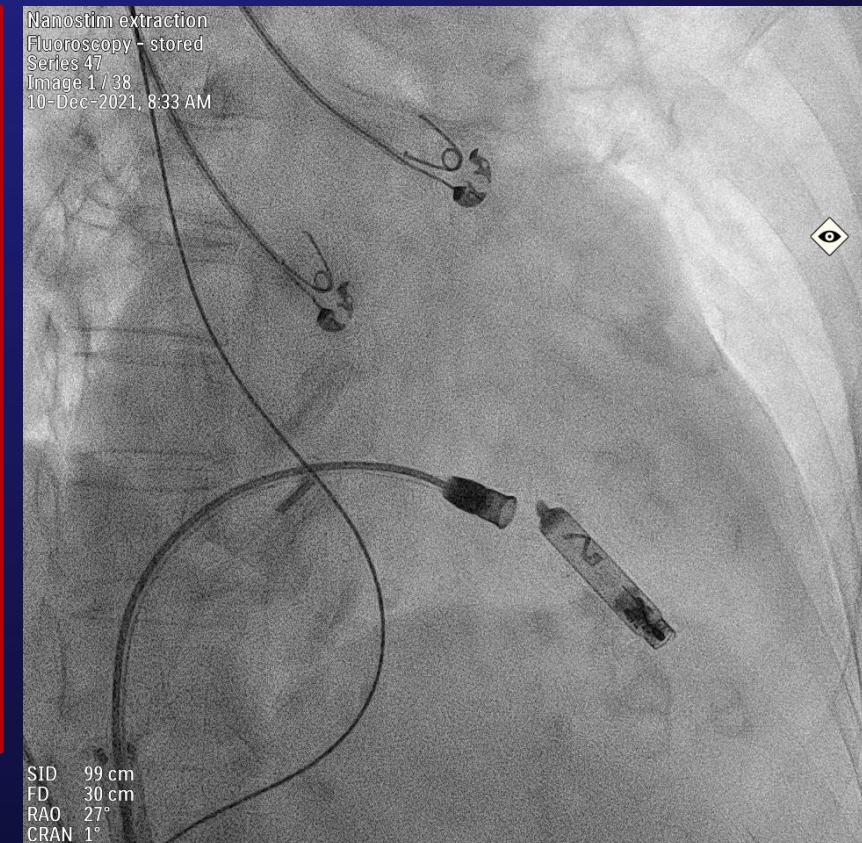
**Higher acute
thresholds:**

2,5 V/0,4 ms

**Waiting period
4 minutes:**

**1,0 V/0,4 ms
Impedance 630 Ω
R wave 9 mV**

Stability test
AVEIR VR Dec 10, 08:33



Case Presentation

TPS Micra Retrieval 1251 days

