# Leadless kardiostimulace:

# PRO !!!

***Petr Neuzil***

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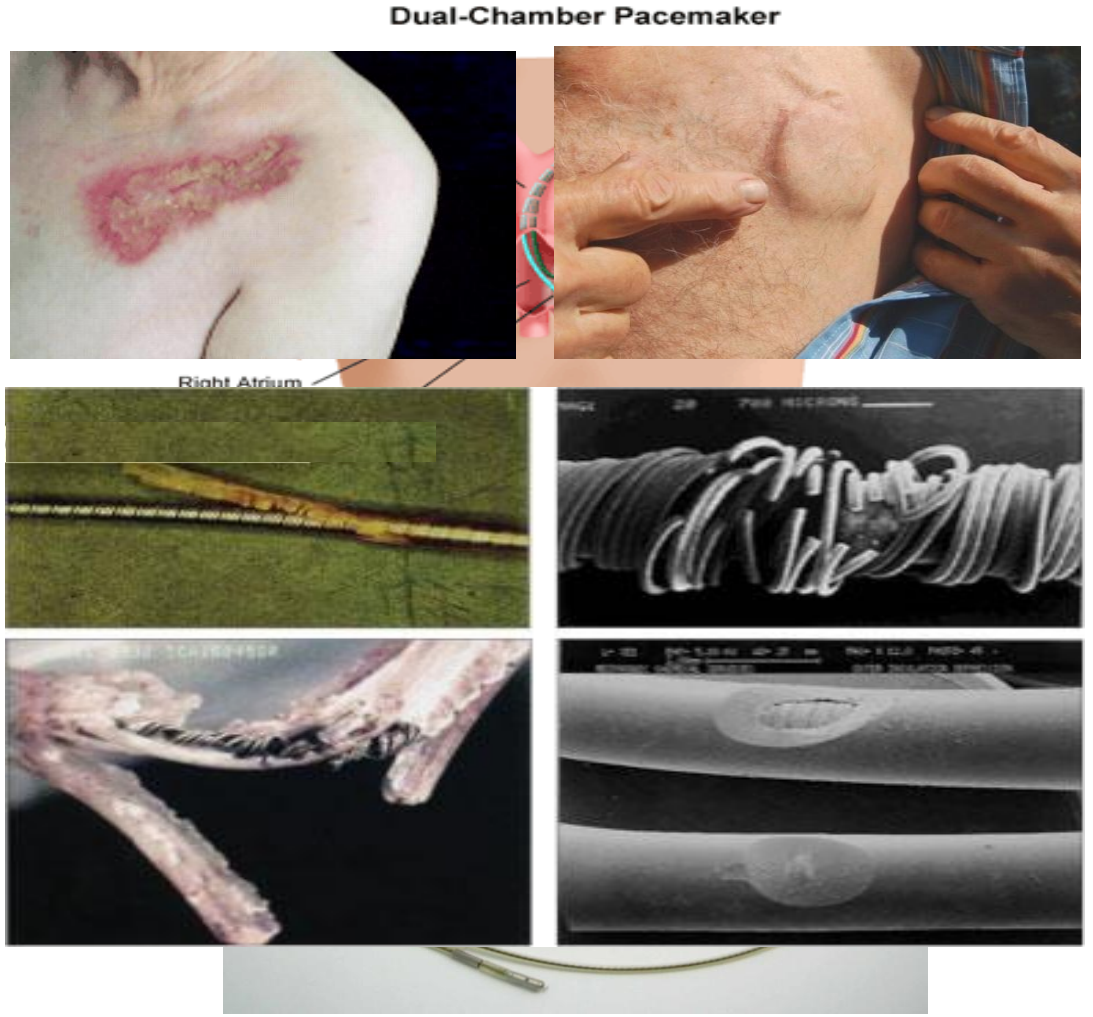
*Prague, Czechia*

1. LÉKAŘSKÁ FAKULTA Univerzita Karlova
NEMOCNICE NA HOMOLCE
KARDIOCENTRUM

# 2025: Pacemaker State-of-the-Art

- **Technology:**
  - Highly mature & reliable
  - Still includes generator, connectors and leads
- **Procedure:**
  - Surgical pocket + Transvenous leads
- **Device issues – Pocket:**
  - Discomfort
  - Hematomas
  - Infections
  - Cosmetic concerns
- Leads
  - Mechanical failures
  - Infections; Extractions
  - Mobility restrictions
  - Some incompatible with MRI




[1] Ellenbogen, K et al. Am J Cardiology, 2003; 92:740–749.
[2] Connolly, SJ et al. The New England journal of Medicine, 2000; 342:1385-91.
[3] Udo, EO et al. Heart Rhythm. 2012;9:728 –735.

# 2025: Pacemaker State-of-the-Art

- Celosvětově je během jednoho roku provedeno 900.000 implantací
- Až 50.000 různých komplikací souvisejících s výkonem
- Odhaduje se, že celosvětově má KS systém 6.4 mil.pacientů
  - ➢ Nicméně až 85.000 nemocných má komplikace s chronicky zavedeným vodičem-elektrodou

| Komplikace s KS systémem | Průměrné navýšení ceny za provedenou intervenci (2009) |
|---|---|
| Infekce | $ 49,652 |
| Revize vodiče-elektrody | $ 16,285 |
| Pneumotorax | $ 16,411 |
| Revize uložení KS přístroje | $ 12,560 |

J Thorac Cardiovasc Surg 1996;111:742-752.
Am J Cardiology 2000;85:774-776.
Cost index: www.bls.gov/cpi/cpid09av.pdf

1: Didier Klug, *Circulation*, 2007
2; MDT, STJ, BSX Product Performance Reports
3: Danish Pacemaker Registry, www.pacemaker.dk

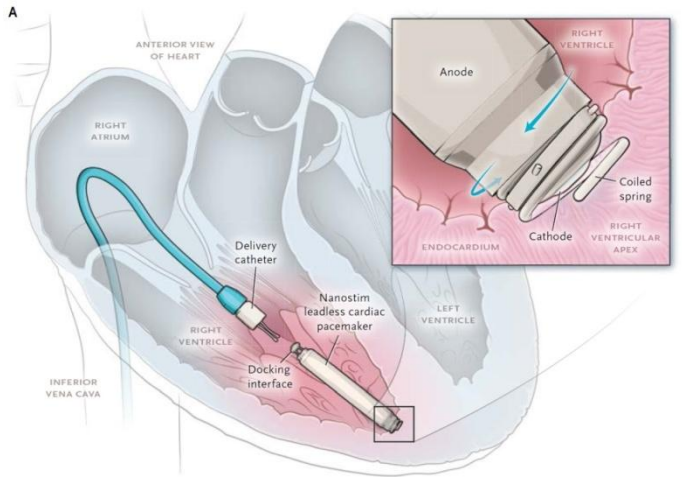
# „LEADLESS“ EVIDENCE BASED MEDICINE

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 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*



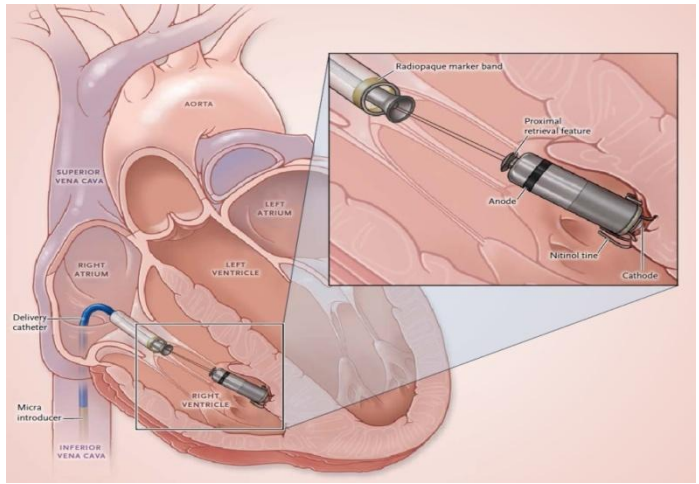

Reddy VY et al: NEJM 2015, Sept 17, 373: 1127.

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 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*



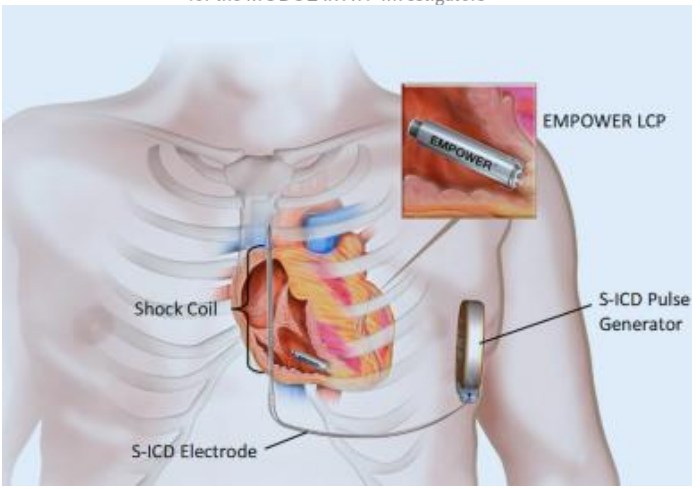

Reynolds D et al: NEJM 2016, Feb 11 : 535.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## A Modular Communicative Leadless Pacing–Defibrillator System

R.E. Knops, M.S. Lloyd, P.R. Roberts, D.J. Wright, L.V.A. Boersma, R. Doshi, P.A. Friedman, P. Neuzil, C. Blomström-Lundqvist, M.G. Bongiorni, M.C. Burke, D. Gras, S.P. Kutalek, A.K. Amin, E.Y. Fu, L.M. Epstein, J.M. Tolosana, T.D. Callahan, J.D. Aasbo, R. Augostini, H. Manyam, D.G. Nair, B. Mondésert, W.W. Su, C. Pepper, M.A. Miller, J. Grammes, K. Saleh, C. Marquie, F.M. Merchant, Y.-M. Cha, C. Cunnington, D.S. Frankel, J. West, E. Matznick, B. Swackhamer, A.J. Brisben, J. Weinstock, K.M. Stein, V.Y. Reddy, and L. Mont, for the MODULAR ATP Investigators*




Knops, RE et al: NEJM 2024, May 18 : 391.

# EVOLUCE TV A „LEADLESS“ KARDIOSTIMULACE

## 1958 - 2025

## 2012 - 2025

# NNH: zkušenosti jednoho centra

| | Leadless pacing v NNH: 2012 - 2024 |
|---|---|
| Σ | **621** **Micra TPS, Micra AV, Nanostim, Aveir VR, Aveir DR, Empower** |
| Věk | 70,5 (20 – 90) let |
| Muži | 56,5% |
| Úspěšnost | 99% |
| Stimulační parametry | Stim.práh: < 1,5 V / 0,25ms Velikost vlny R: 8 – 20 mV |
| Jiná než VVI stim. | **Micra AV, Aveir DR,WiCS** |
| Komplikace | **0,6 % 4 x dislokace**<br>**0,3 % 2 x srdeční tamponáda**<br>**0 % revize třísla, infekce, smrt** |

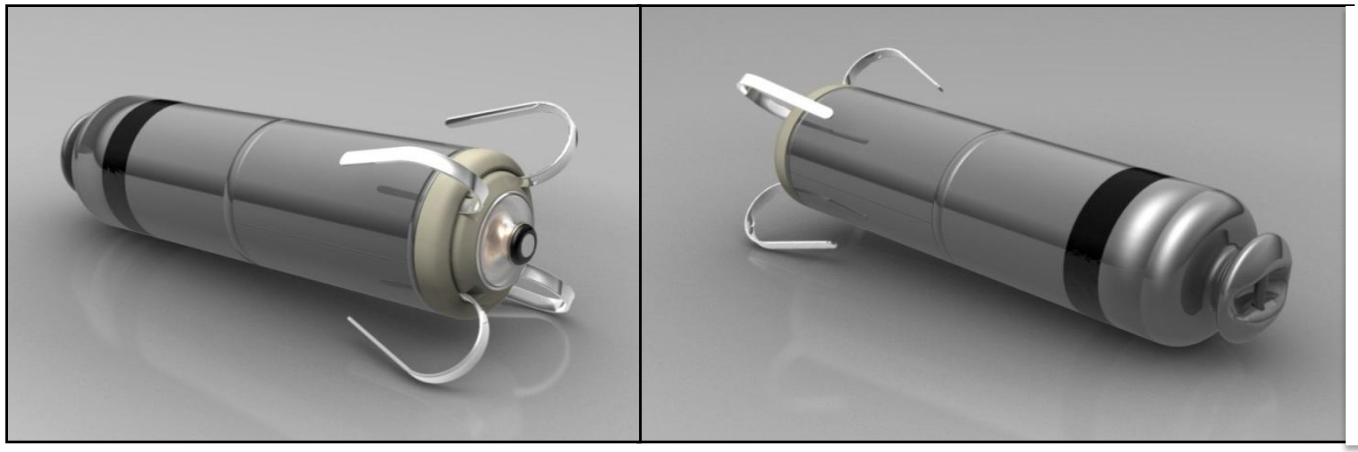

Mute
Stop Video
Security
Participants
3
Chat
Petr
Neužil
Josef
Kautzner


Mute
Stop Video
Security
Participants
3
Chat
Share Screen
Petr
Neužil
Josef
Kautzner


Mute
Stop Video
Security
Participants
3
Chat
Petr
Neužil
Josef
Kautzner

# Fyziologická jednodutinová stimulace

## *Micra AV : od VVI k DDD*



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

## Micra Atrial TRacking Using a Ventricular AccELerometer Study

*NCT03157297*

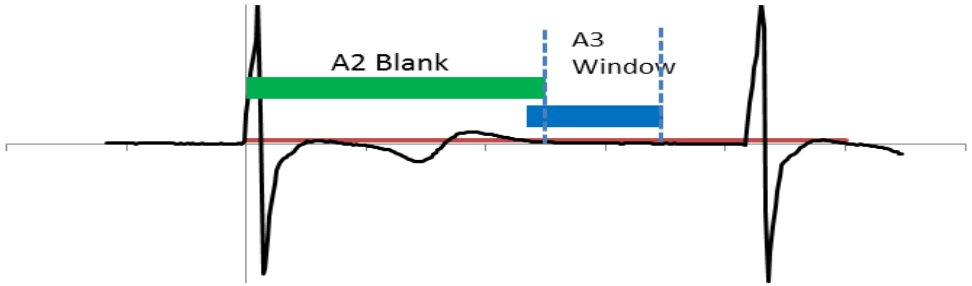
**Primary Endpoint :**

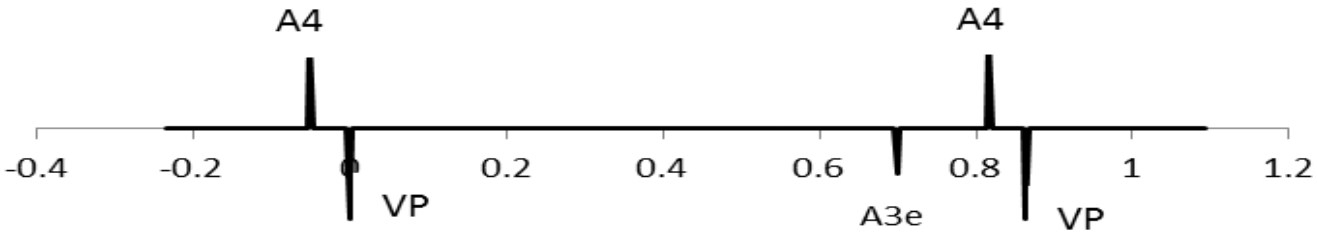
**S**ynchronisation of ventricular pacing to reach = VDD

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

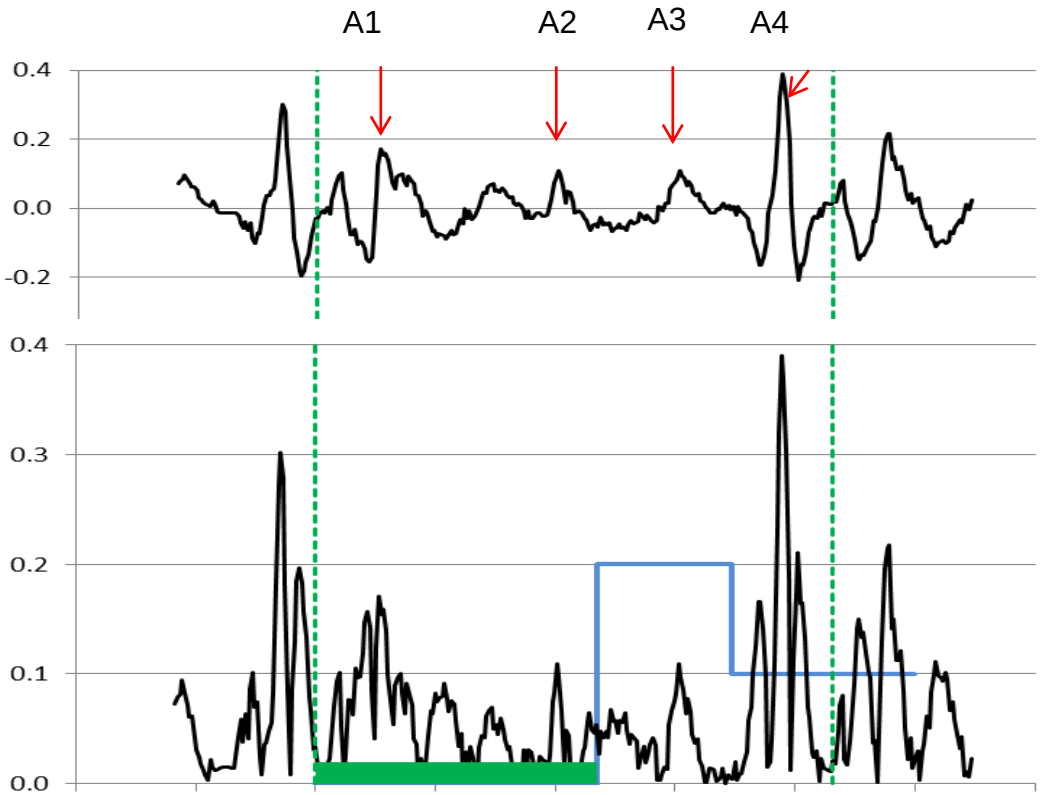
# Micra AV : VDD mode

## *Detekce pohybu cípů TCH*



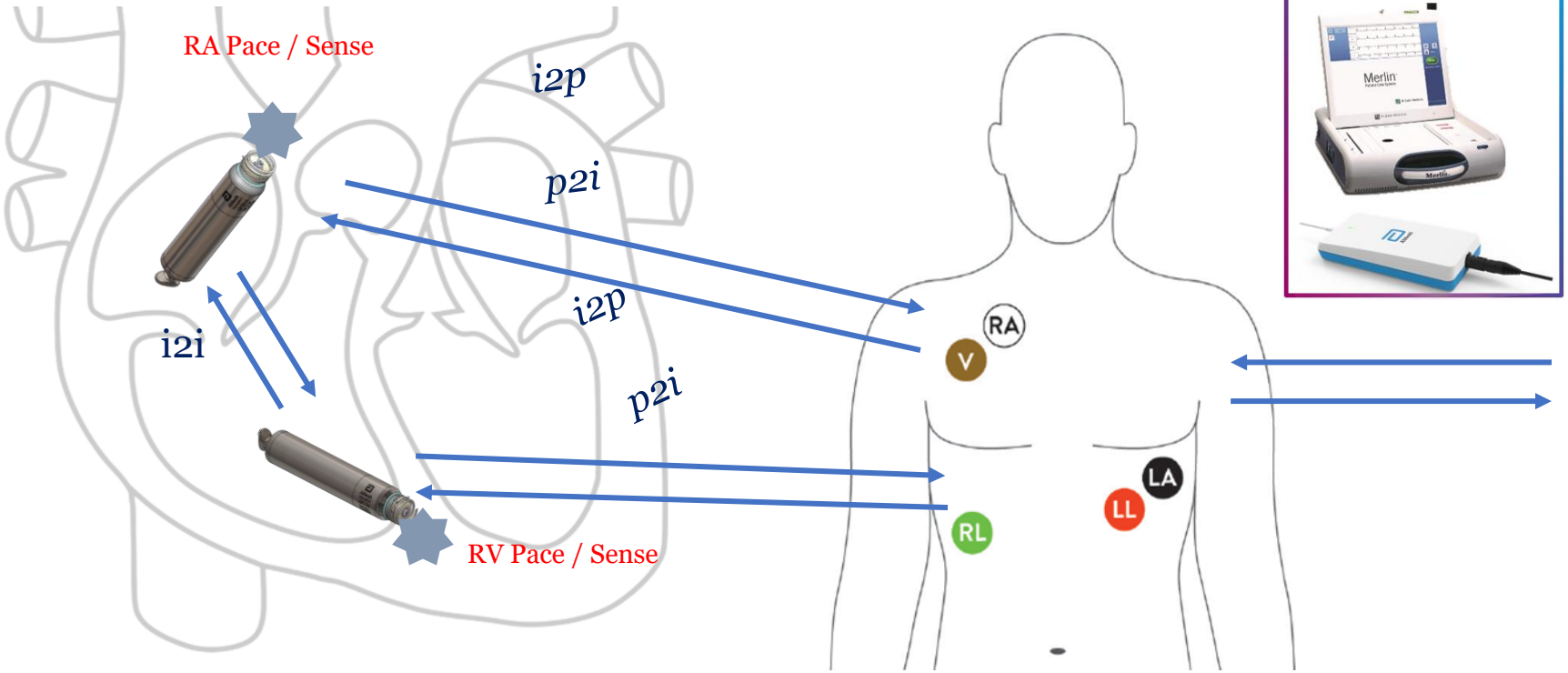

- „High pass“ filtr accelerometer (5-10Hz) – 3 x→ 360°
- Usměrňovací filtr
- Blanking after ventricle activity
- Blanking or increasing threshold post T- wave detection to erase A3 false detection
  - Measurement → hardware
    Blanking → firmware
- A4 wave detection as the first wave ovecross the filter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



# Dvoudutinový leadless Aveir DR

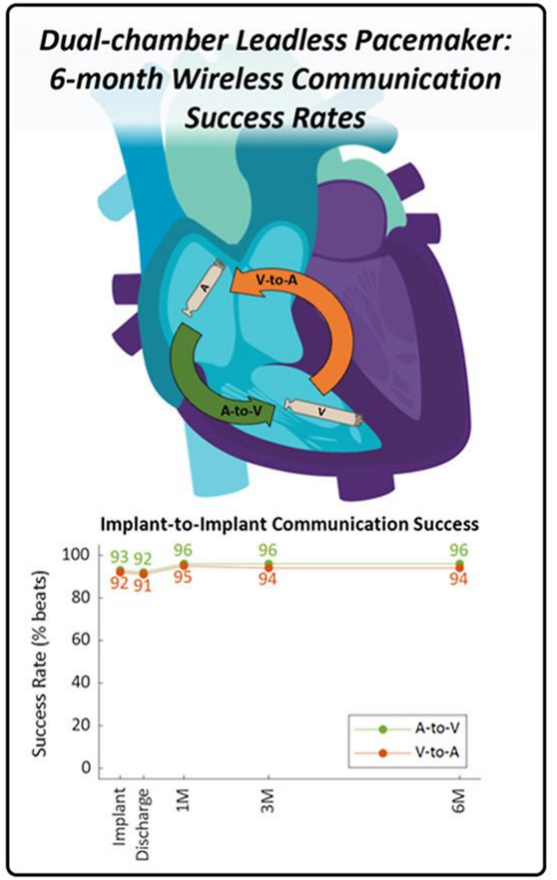
*vzájemná komunikace „i2i“ (implant to implant)*

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







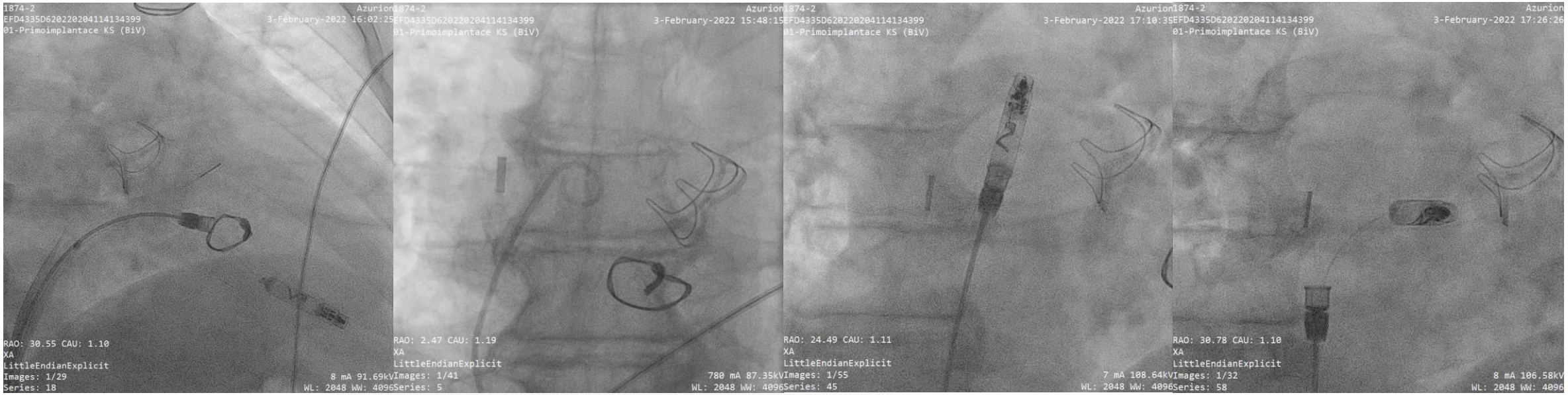


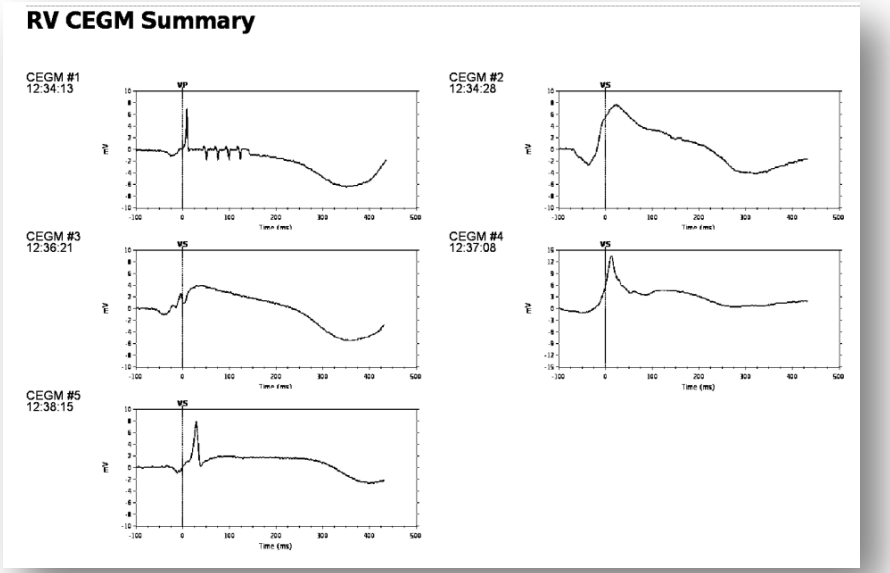


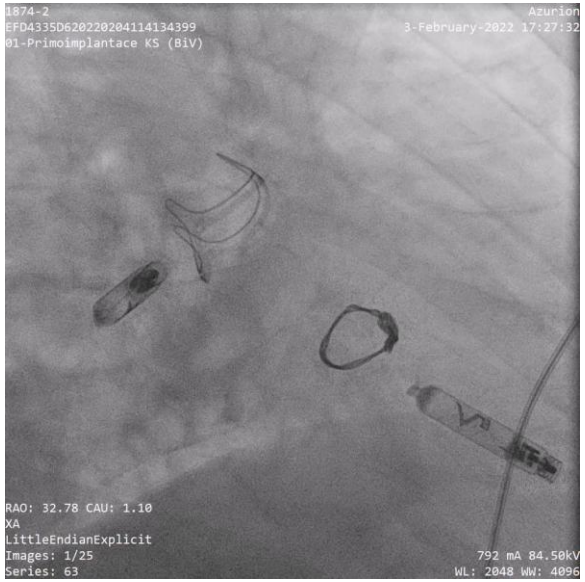
Cantillon DJ/NeuzilP/Knops R/Reddy VY et al“ Circulation EP 2022
Doshi RN/Neuzil P/Reddy VY et al: Heart Rhythm 2025, 22; 1010-1020

# Dvoudutinový leadless Aveir DR

## *implantace komorové a síňové komponenty*

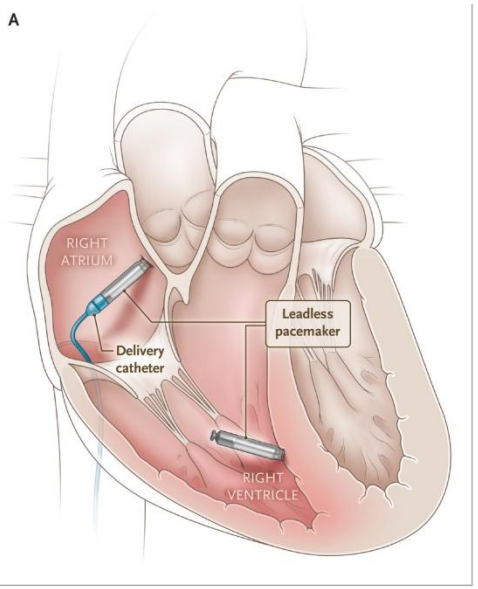


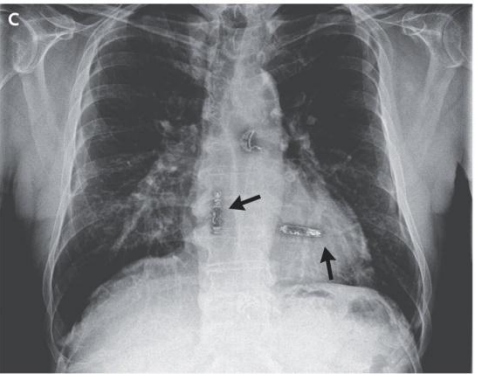



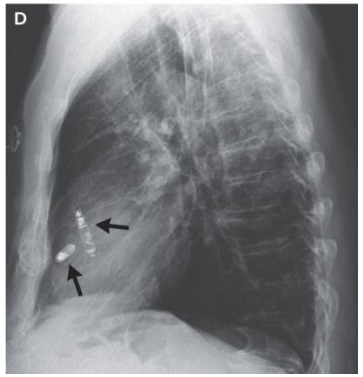
# Dvoudutinový leadless Aveir DR

## *"I2I" algoritmus komunikace*








The NEW ENGLAND JOURNAL of MEDICINE

CURRENT ISSUE SPECIALTIES TOPICS

ORIGINAL ARTICLE

# A Dual-Chamber Leadless Pacemaker

**Authors**: Reinoud E. Knops, M.D., Ph.D., Vivek Y. Reddy, M.D., James E. Ip, M.D., Rahul Doshi, M.D., Derek V. Exner, M.D., M.P.H., Pascal Defaye, M.D., Robert Canby, M.D., Maria Grazia Bongiorni, M.D., Morio Shoda, M.D., Gerhard Hindricks, M.D., Petr Neužil, M.D., Mayer Rashtian, M.D., Karel T.N. Breeman, M.D., Jordan R. Nevo, M.S., Leonard Ganz, M.D., Chris Hubbard, M.B.A., and Daniel J. Cantillon, M.D., for the Aveir DR i2i Study Investigators* -10 Author Info & Affiliations

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1. LÉKAŘSKÁ FAKULTA Univerzita Karlova

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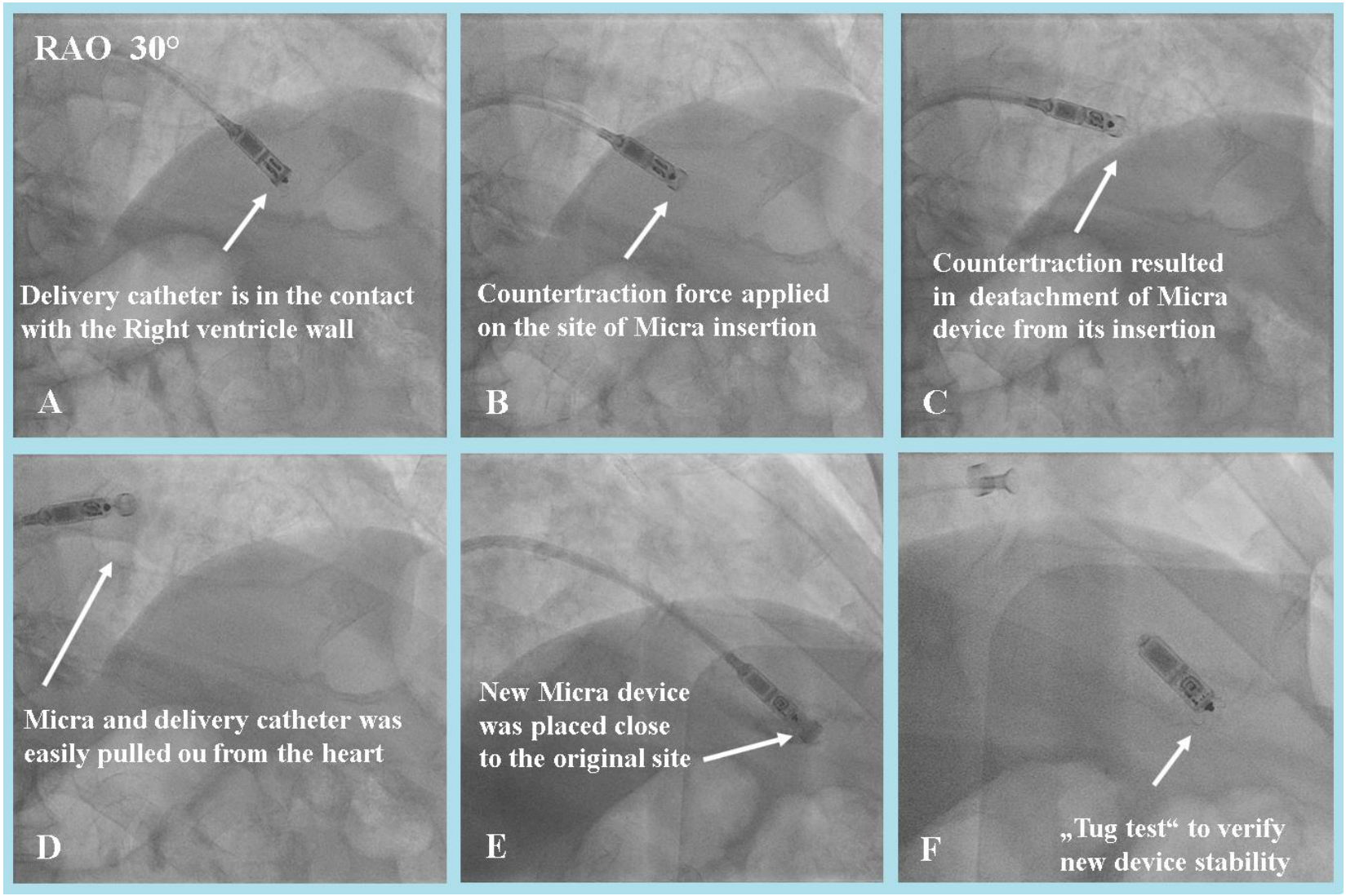
# Postup při extrakci pro MICRA TPS

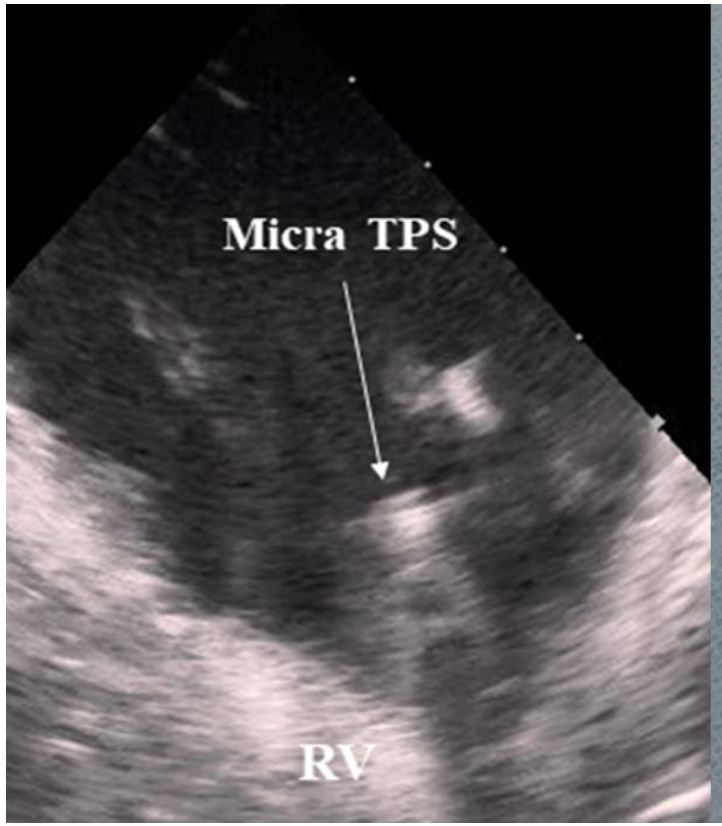


# Extrakce MICRA TPS

*~ 10 let po primoimplantaci*

***Funasako M/ Neuzil P et al:,*** *Europace. 2024 Oct 3;26(10):euae256*

**Delivery katetr se zavedenou kličkou – Ø 7 mm → kontratrakcí uvolnění kotev ( 10 min.)**
**Nekomplikovaná re-implantace nového přístroje Micra VR - excelentní parametry**





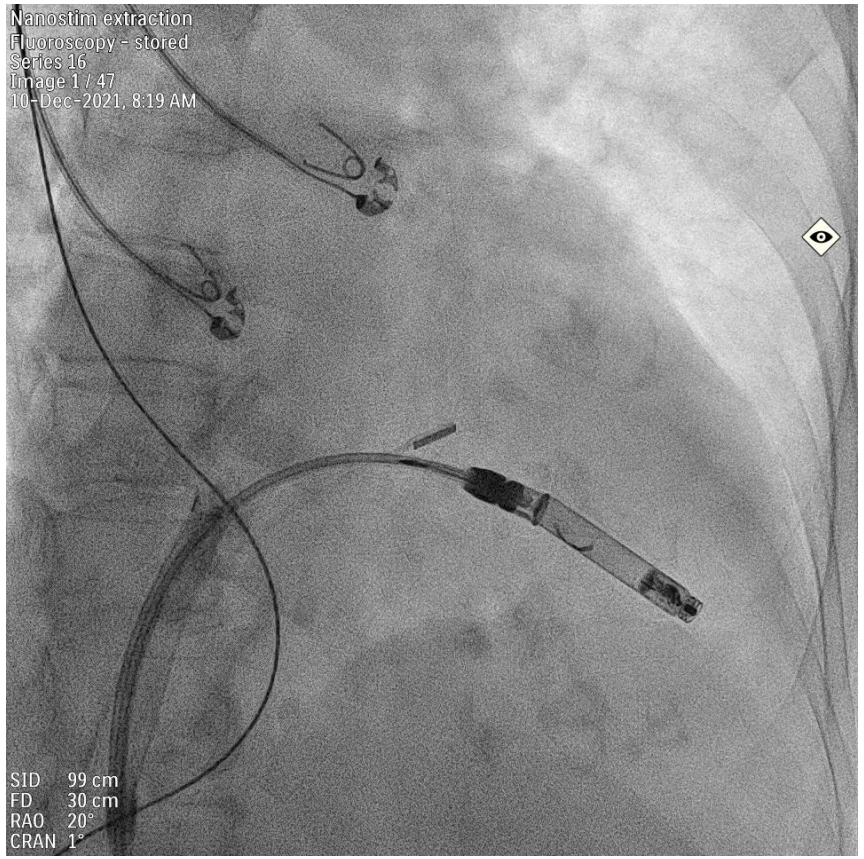
Micra TPS snared with the delivery catheter after successful retrieval


Micra TPS with minimal tissue ingrow over the device

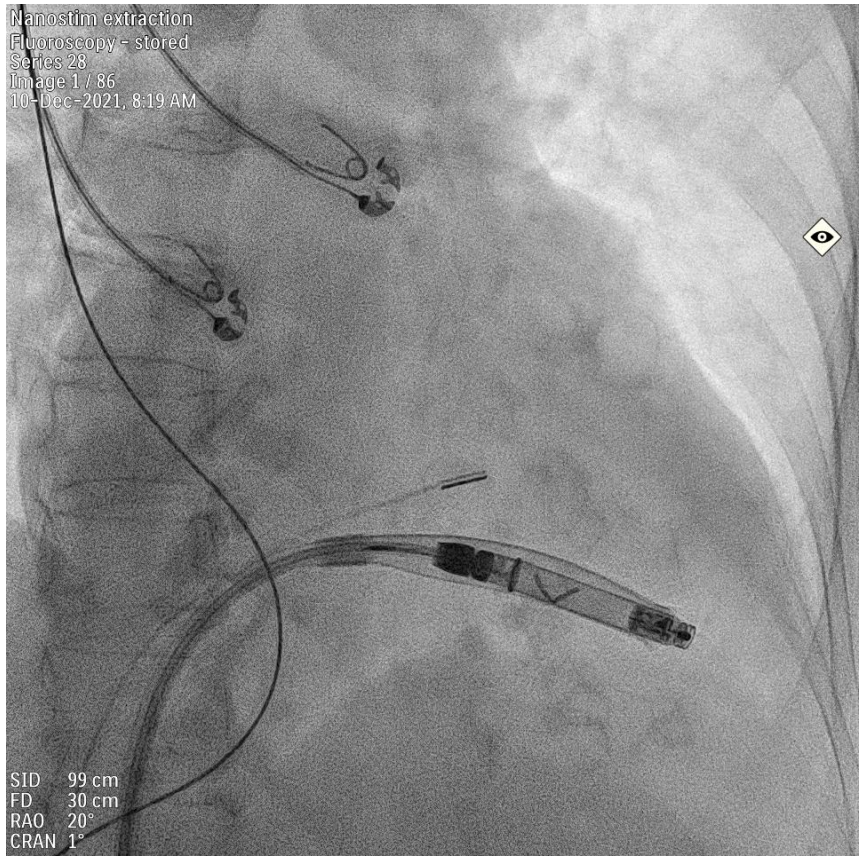
# Case report

*Nanostim LCP retrieval December 10,2021*

**„Meshed“ Sleeve**
**OVER LCP Dec 10, 08:19**



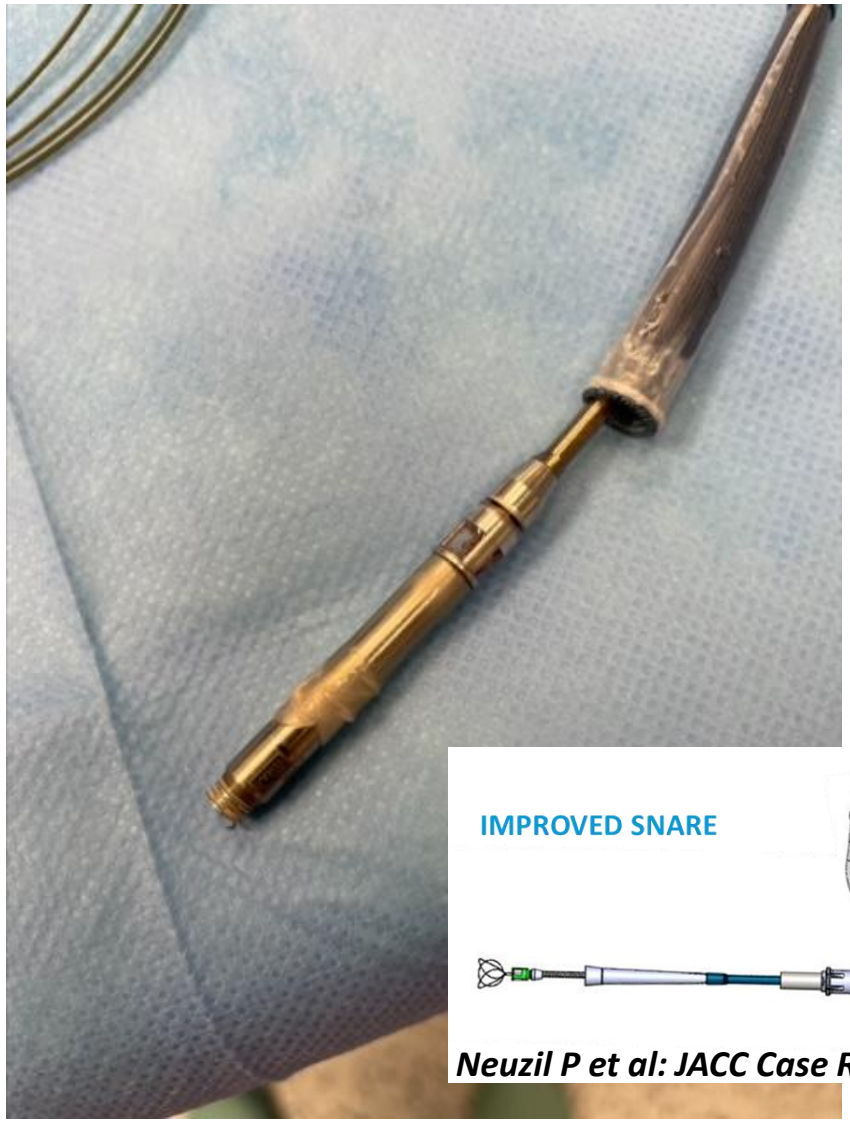

**Rotation and final**
**RELEASE Dec 10, 08:19**

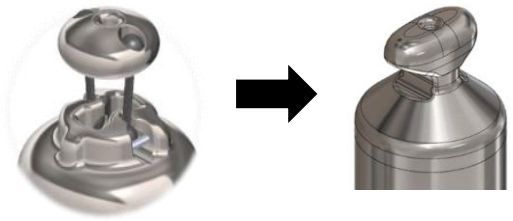


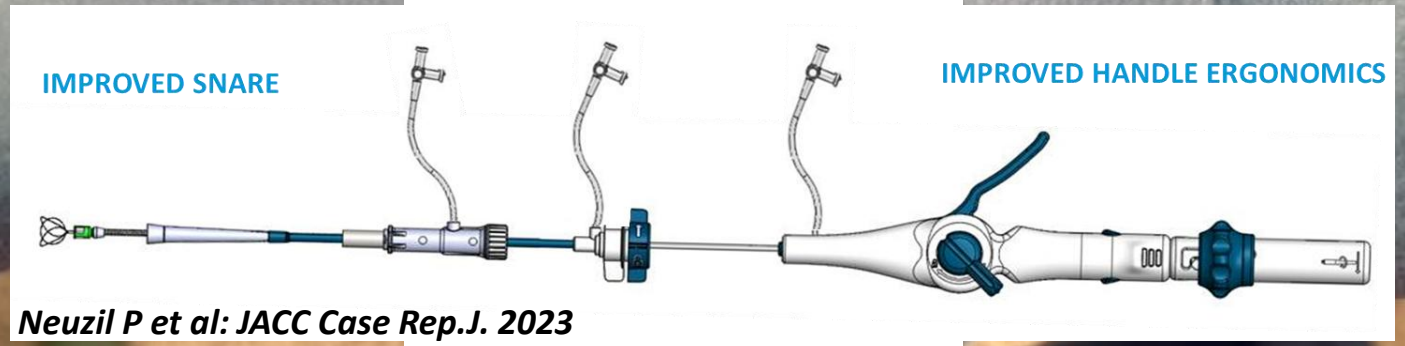

**Neuzil P et al***: HeartRhythm Case Rep. 2023 Feb 3;9(4):258-262*

# Extrakce Nanostim LCP

## *Implantace 17.12.2012 – Extrakce 10.12.2021*





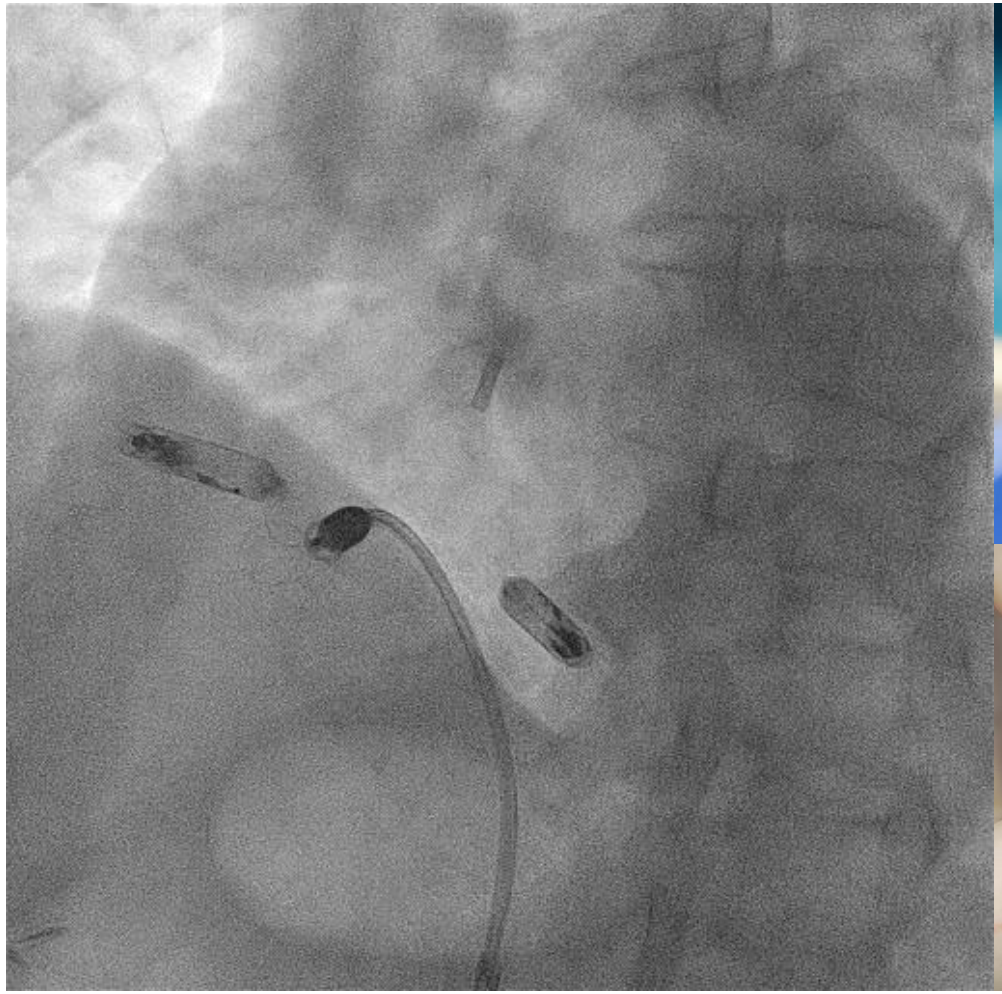


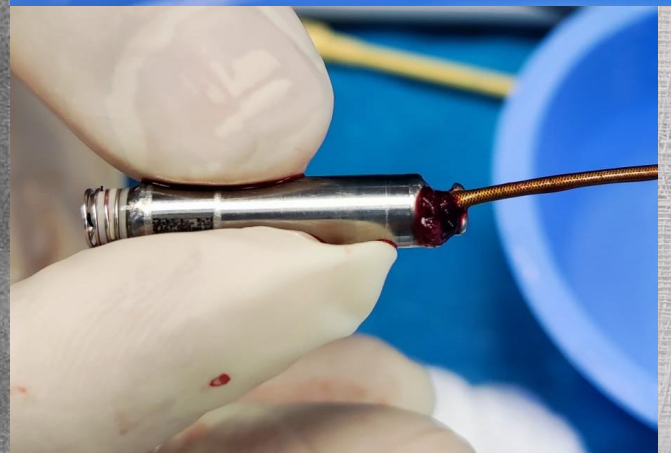

***Neuzil P et al: JACC Case Rep.J. 2023***

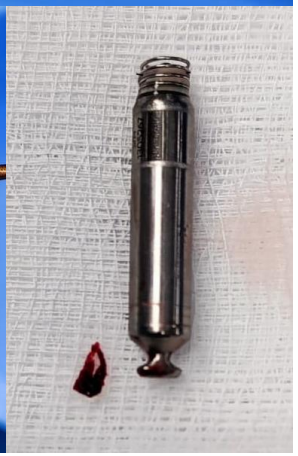
# Extrakce AVEIR DR

## ~ *tromby na síňové komponentě AVEIR*

**„Retriver“ katetr s trojitou kličkou → výkon ( 15 min) obě komponenty úspěšně extrahovány**
**Nekomplikovaná re-implantace transvenózního DDD KS**

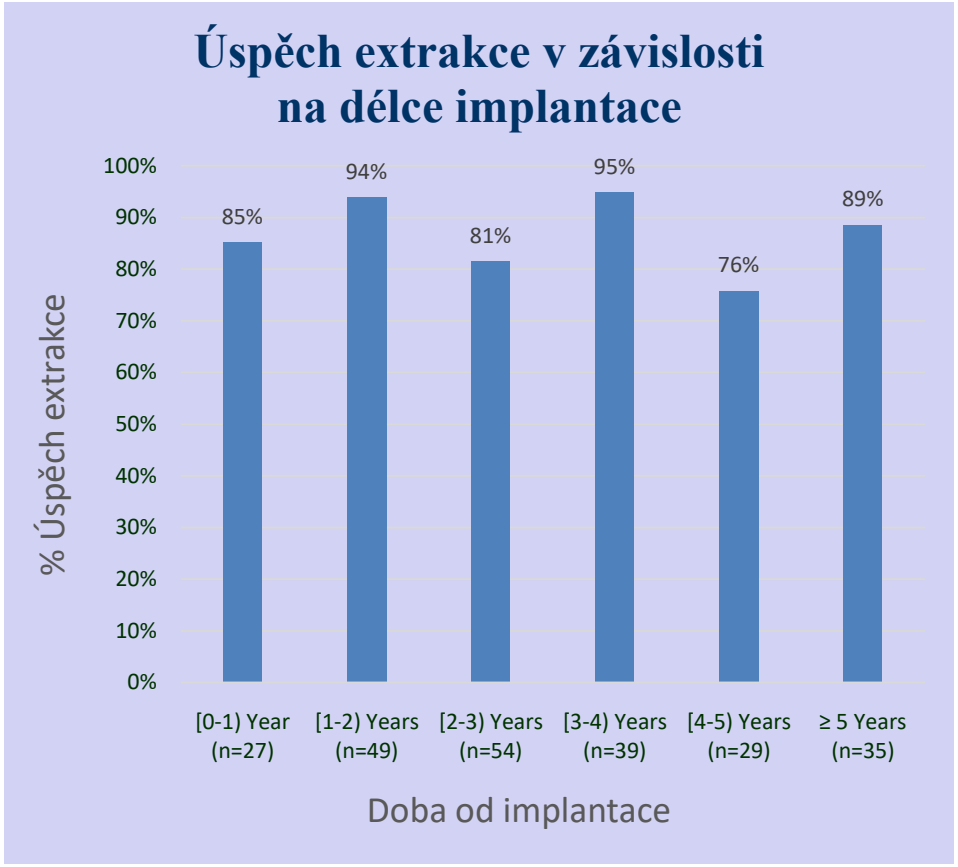


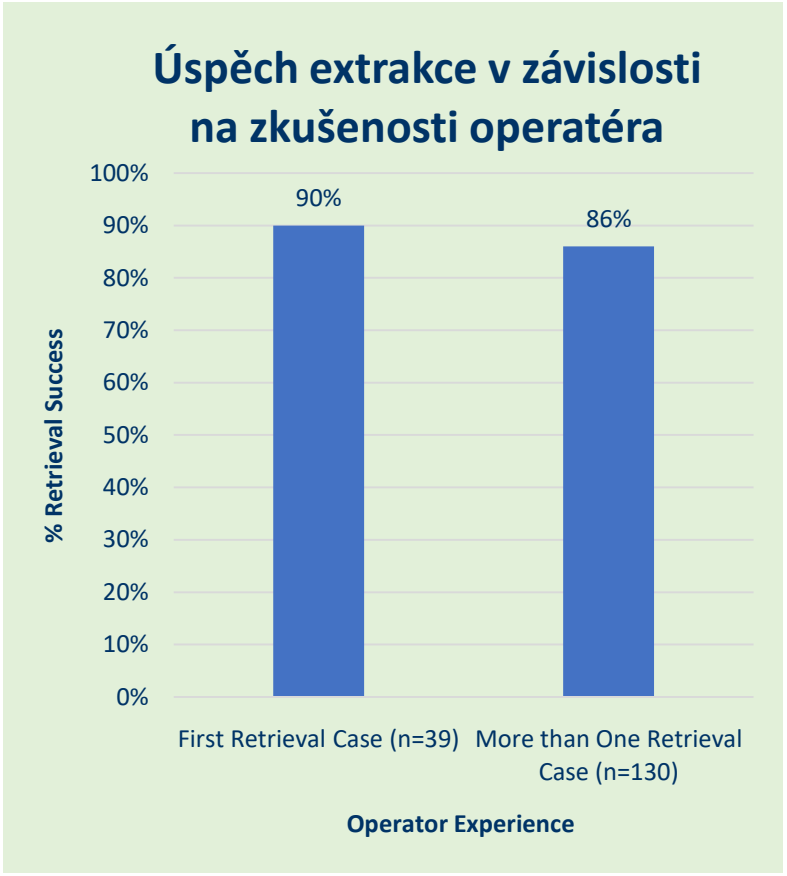




# Celosvětový přehled extrakcí Nanostim

## Délka implantace & zkušenost operatéra *(> 28.10.21)*




**89% (31/35) úspěch u extrakcí LCP ≥ 5 let**

**Není jasná závislost na zkušenosti**

**Neuzil P et al:** J Am Coll Cardiol. 2025 Mar 25;85(11):1111-1120

# 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

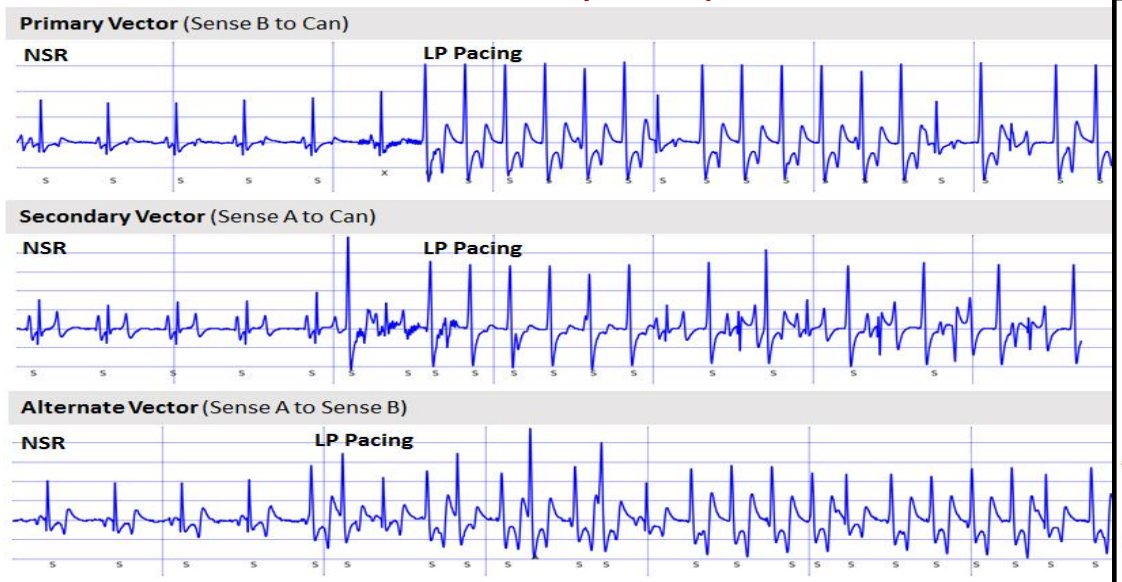
Dedicated retrieval system with single & tri-loop snares


Dedicated delivery and retrieval catheters

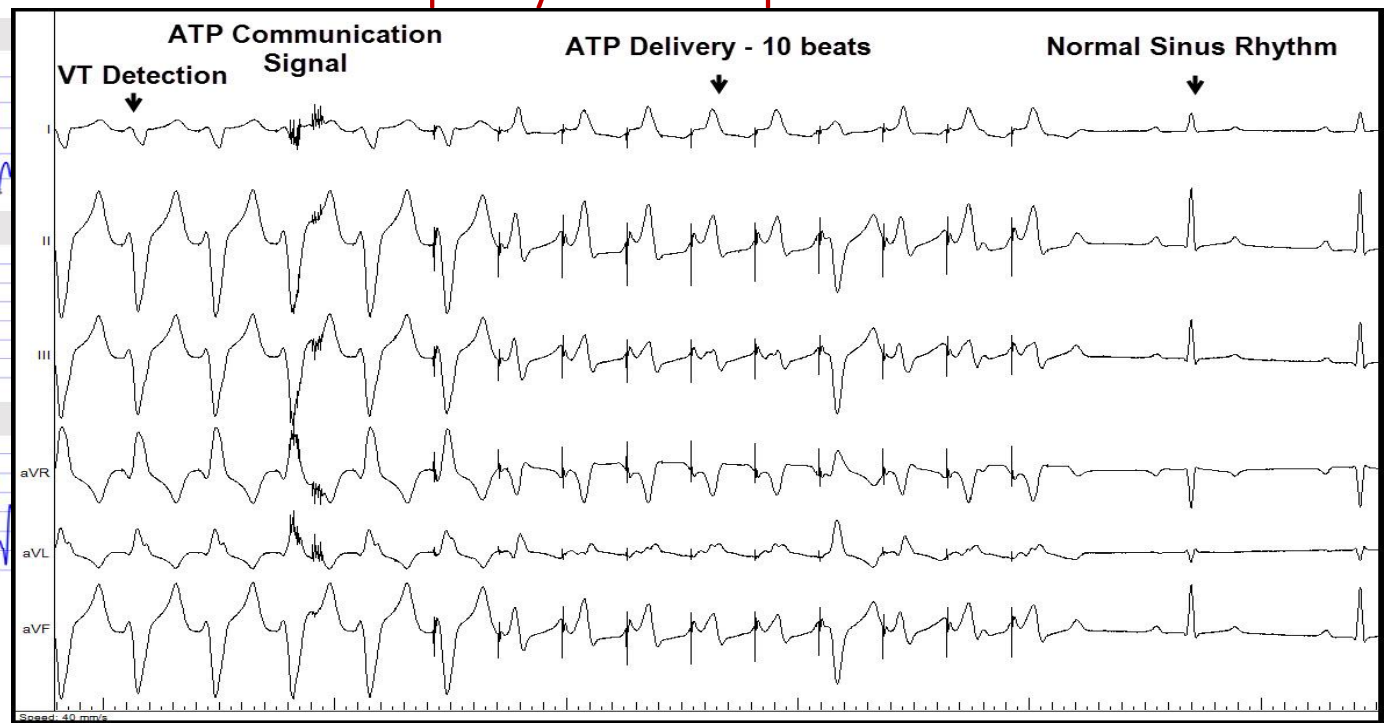
# Komunikace Leadless ATP & S-ICD:

## *Preklinický model*

S-ICD diskriminace rytmu při stimulaci



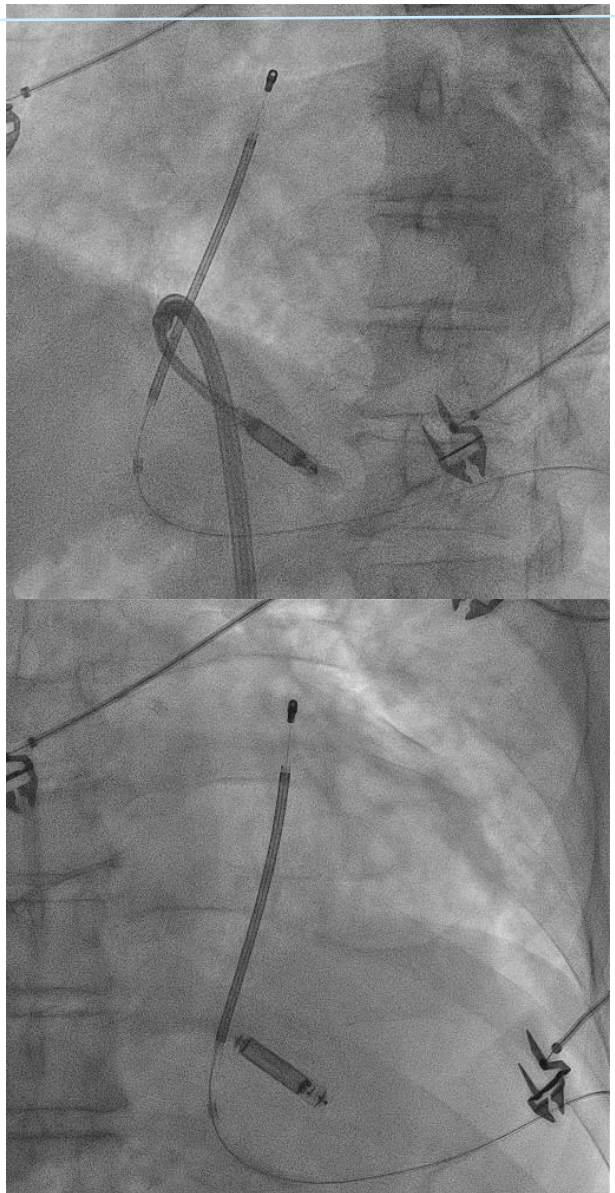

ATP terapie vydaná LCP při detekci S-ICD

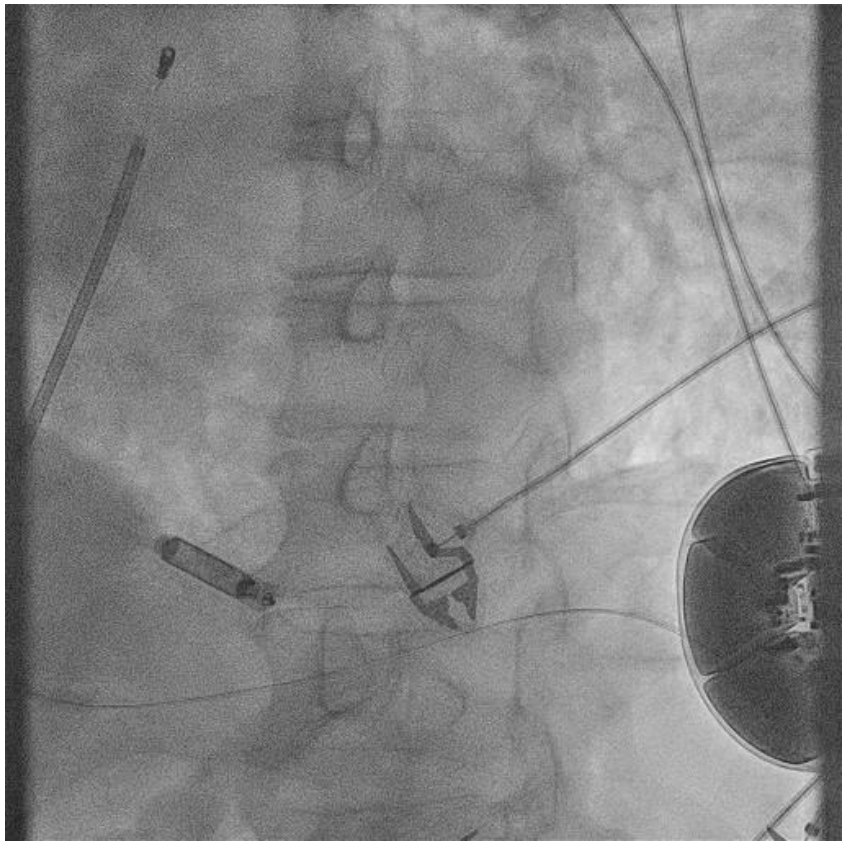


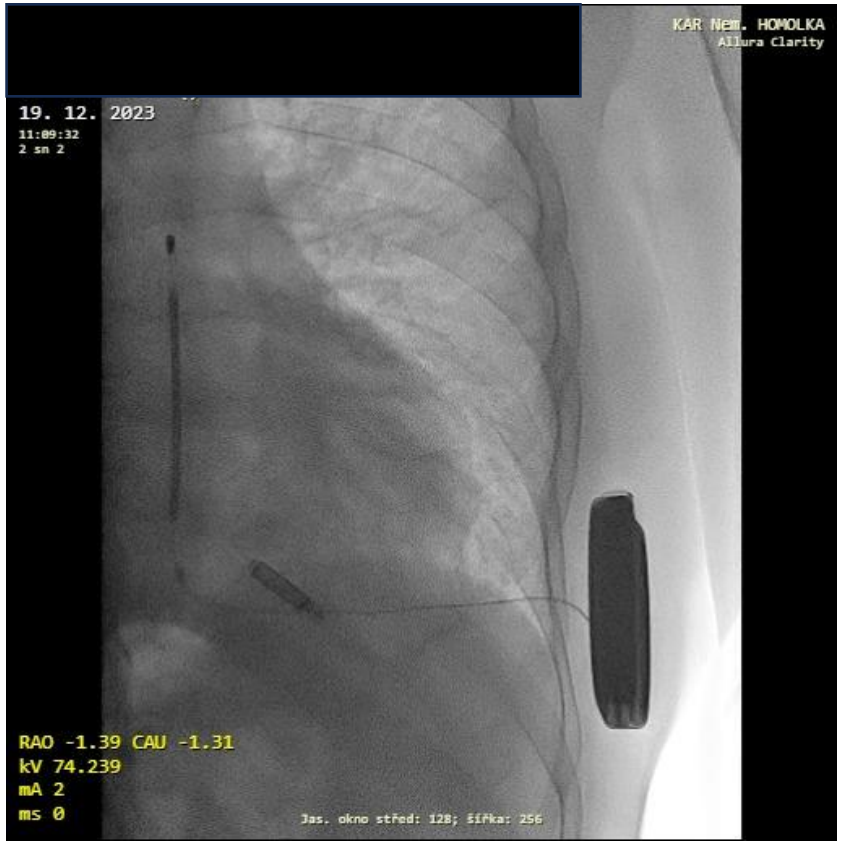

*Tjong F.V.Y. et. al., JACC:CE*

# Komunikace Leadless ATP & S-ICD:

## *Kazuistika*







# Komunikace Leadless ATP & S-ICD:

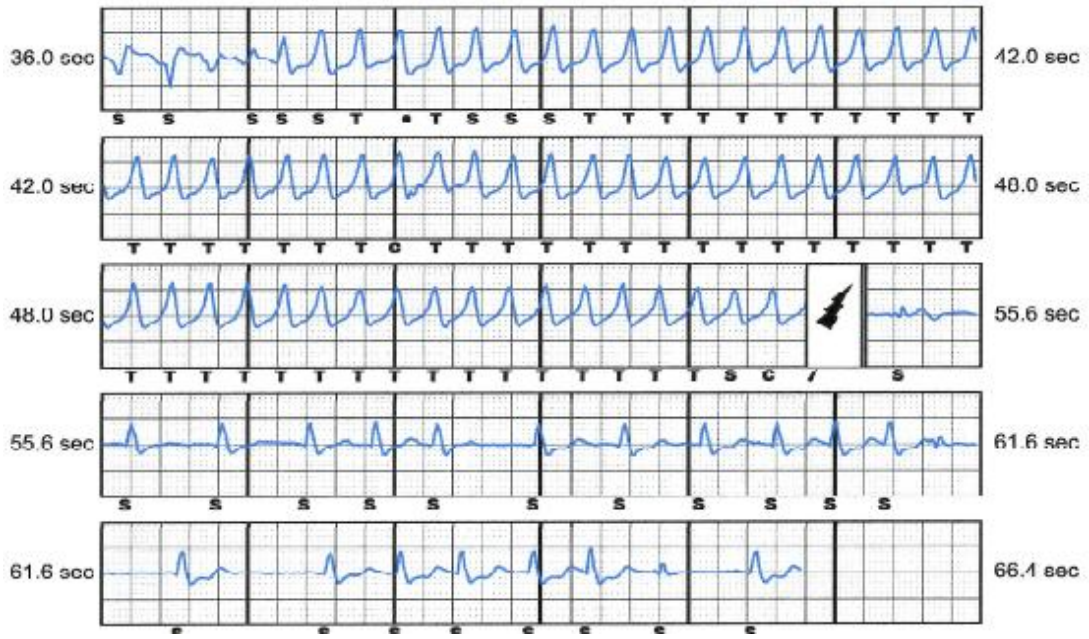
## *Kazuistika*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

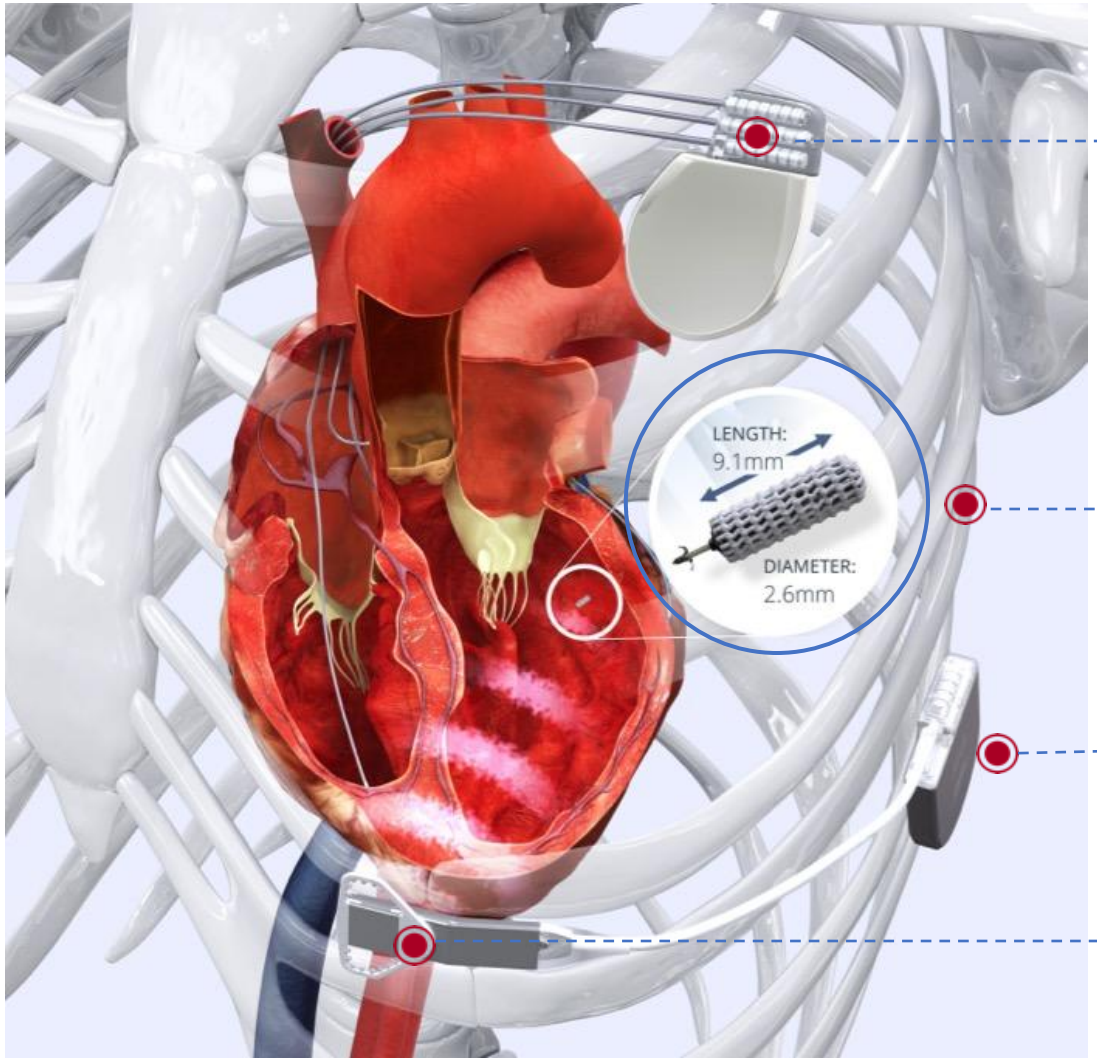
## A Modular Communicative Leadless Pacing–Defibrillator System

R.E. Knops, M.S. Lloyd, P.R. Roberts, D.J. Wright, L.V.A. Boersma, R. Doshi, P.A. Friedman, P. Neuzil, C. Blomström-Lundqvist, M.G. Bongiorni, M.C. Burke, D. Gras, S.P. Kutalek, A.K. Amin, E.Y. Fu, L.M. Epstein, J.M. Tolosana, T.D. Callahan, J.D. Aasbo, R. Augostini, H. Manyam, D.G. Nair, B. Mondésert, W.W. Su, C. Pepper, M.A. Miller, J. Grammes, K. Saleh, C. Marquie, F.M. Merchant, Y.-M. Cha, C. Cunnington, D.S. Frankel, J. West, E. Matznick, B. Swackhamer, A.J. Brisben, J. Weinstock, K.M. Stein, V.Y. Reddy, and L. Mont, for the MODULAR ATP Investigators*



# WiSE CRT System

*Hlavní součásti a princip „wireless“ stimulace*

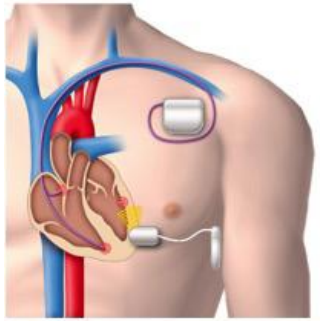


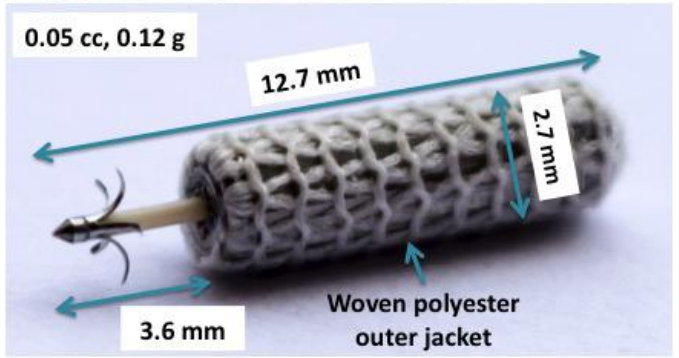

CO-IMPLANT DEVICE

RECEIVER ELECTRODE

BATTERY

TRANSMITTER



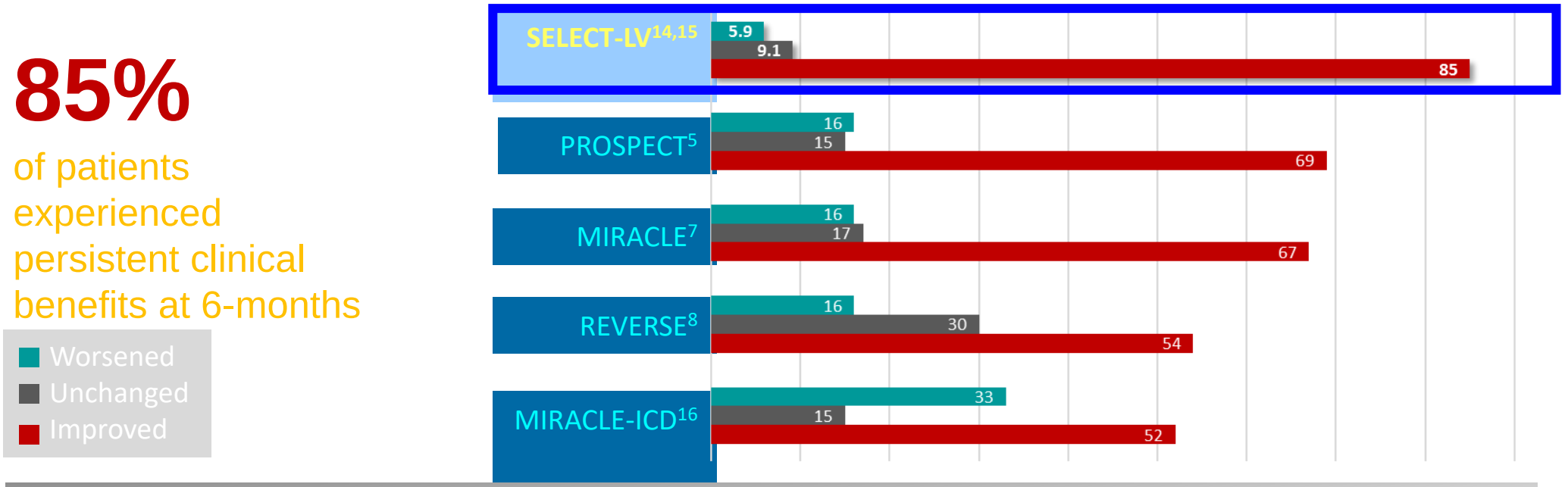


# Studie SELECT-LV :
## *Hlavní výsledky*

**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



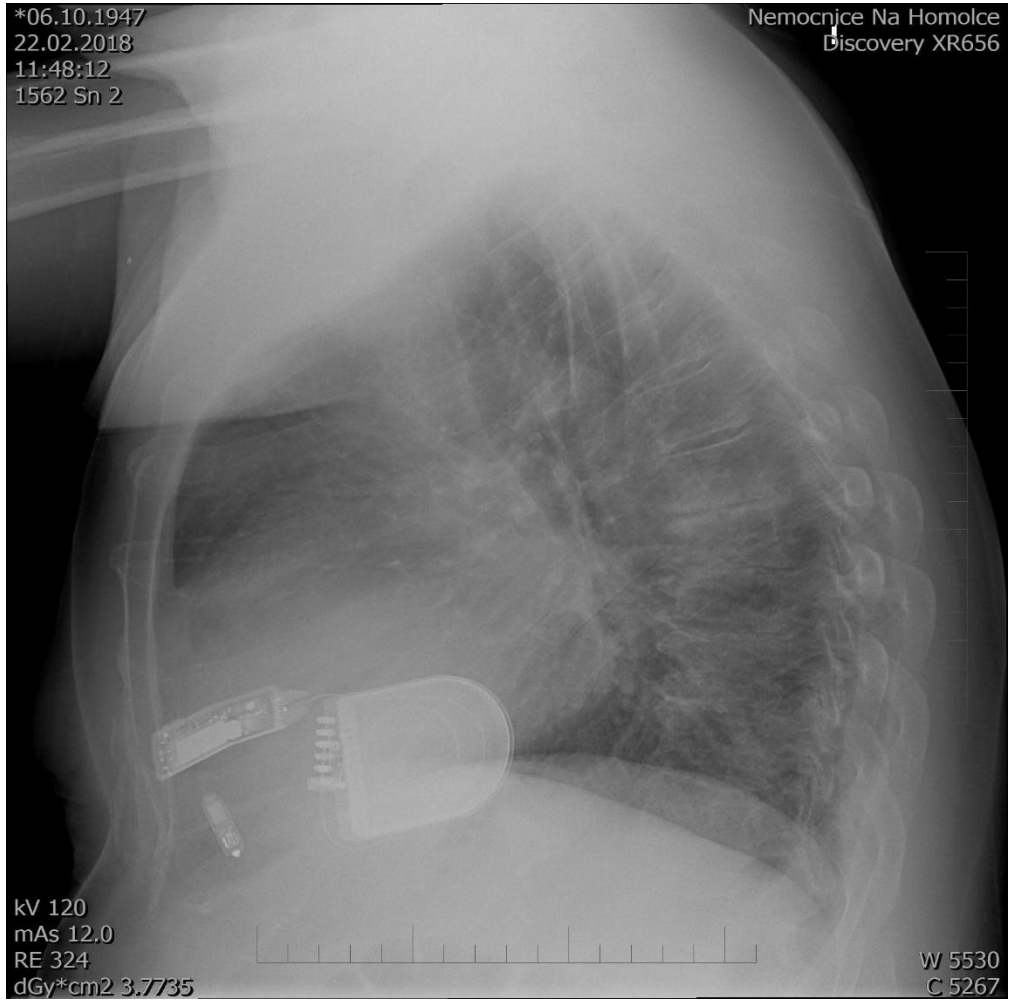

***This pts group had previously failed conventional CRT***

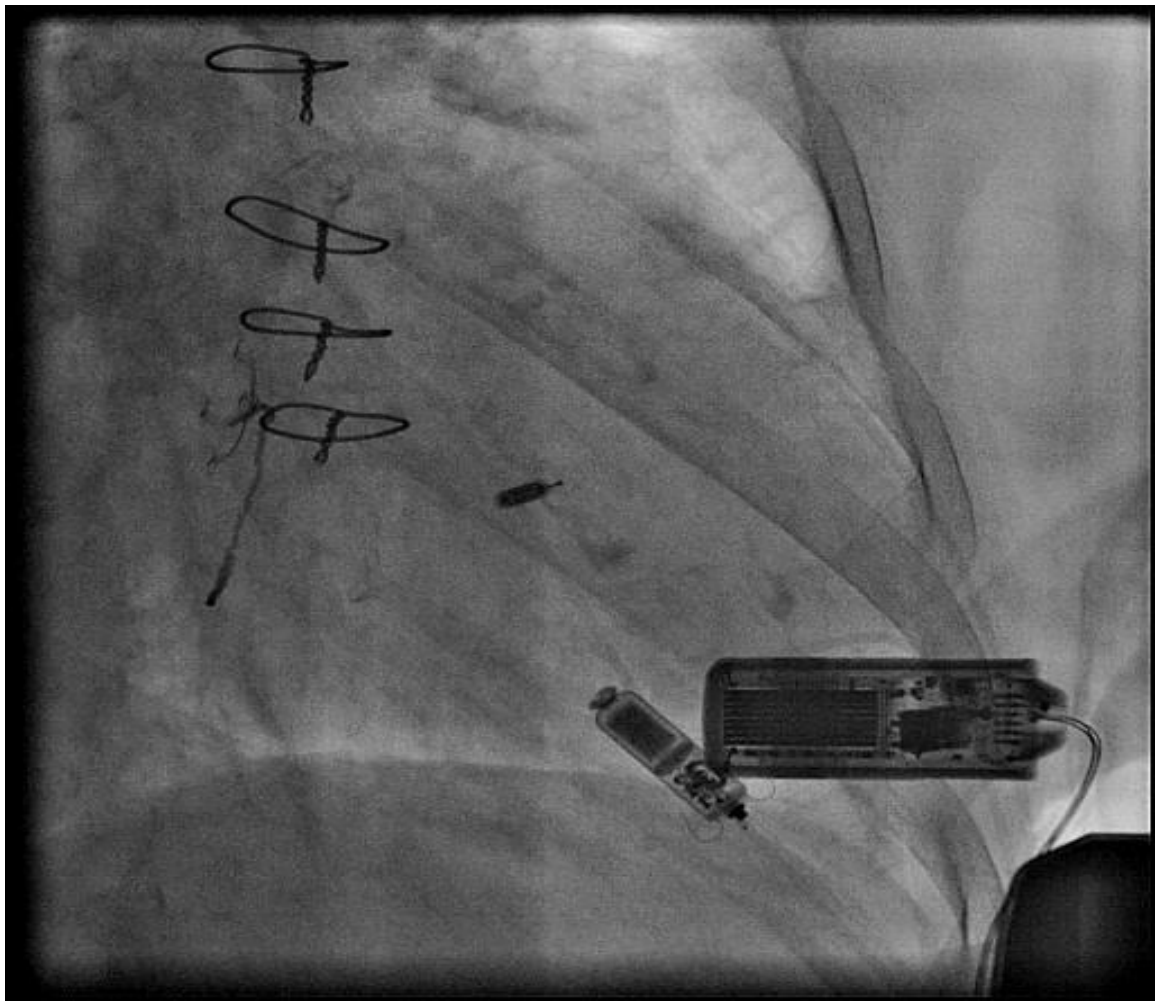
*Reddy VY/Neuzil P/Riahi S: JACC 2017;69:2119-2129*

# Kompletní leadles-wireless CRT systém

## *Micra TPS + WiSE*

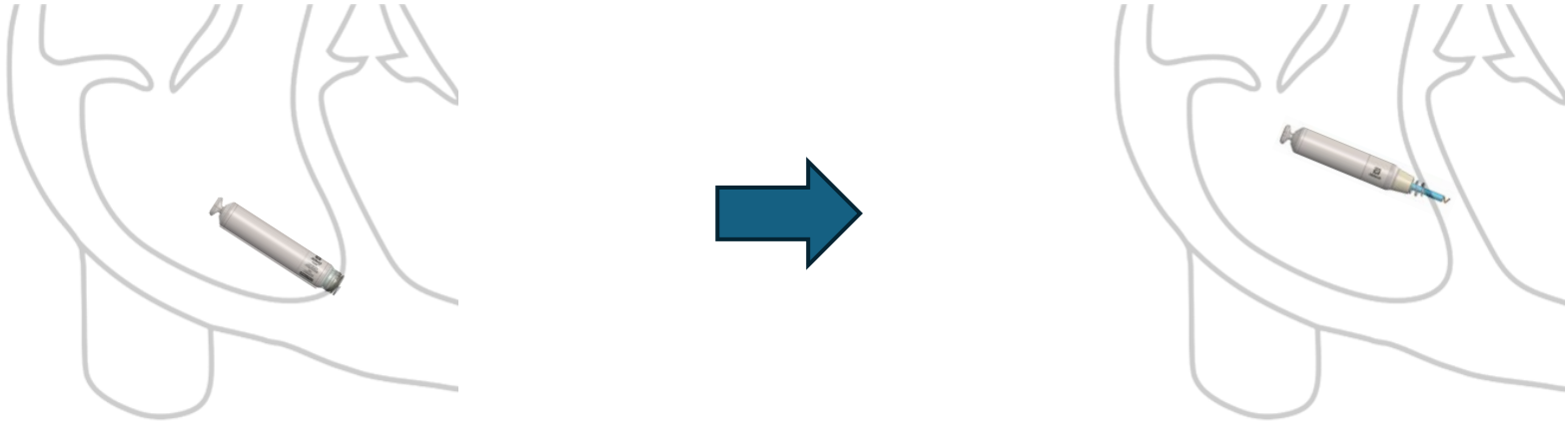
*Carabelli A / Neuzil P / DefayeP: Europace 2021;23:740-747*



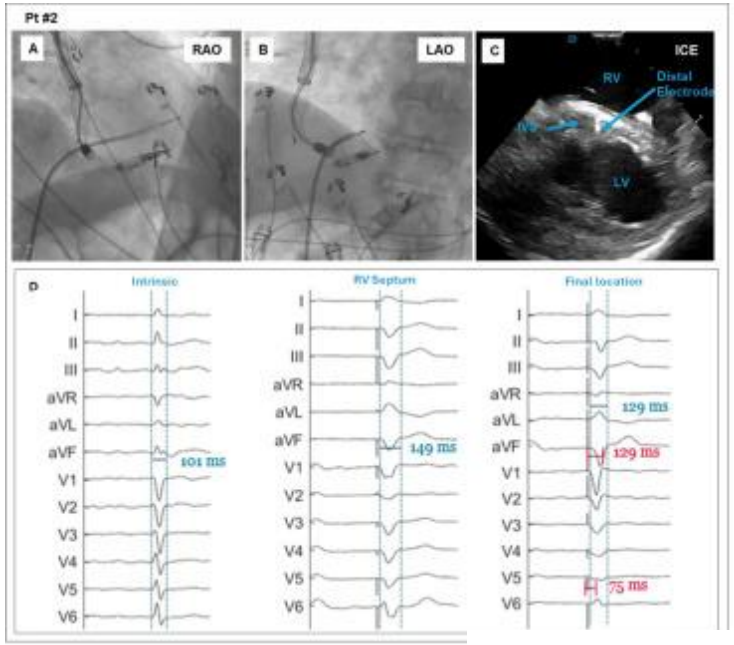
# F-I-M Study of a Leadless Pacemaker System for Left Bundle Branch Area Pacing

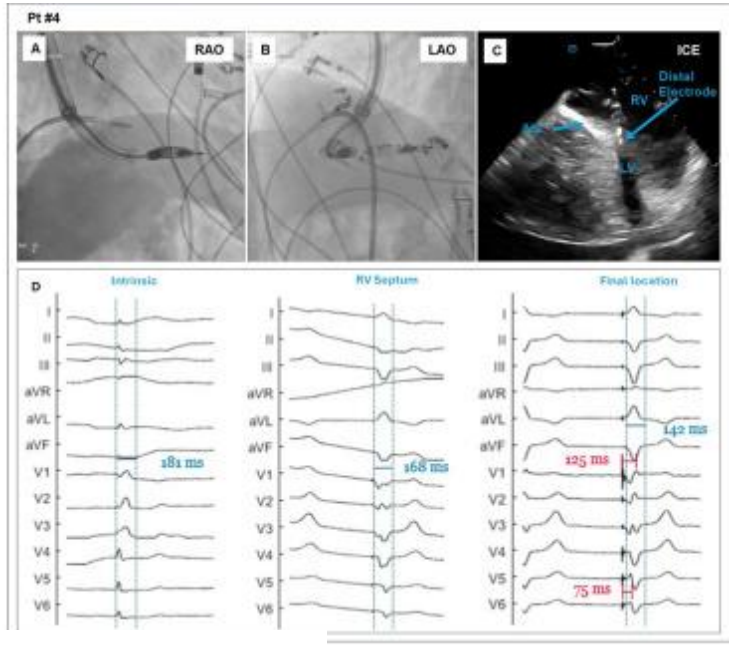
- Leadless pacing has already demonstrated significant benefits to patients
- Current ventricular leadless pacemakers are limited to right ventricular pacing and cannot perform left bundle branch area pacing (LBBAP)
- A novel helix-based leadless pacemaker has been developed for LBBAP that combines the benefits of leadless pacemaker technology with that of conduction system pacing ($LP_{CSP}$).



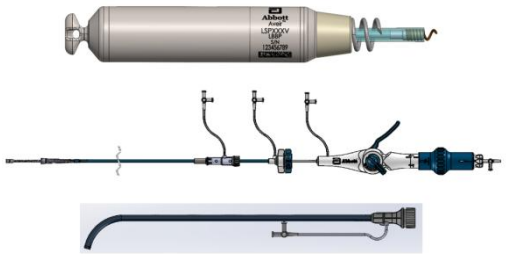
# F-I-M Study of a Leadless Pacemaker System for Left Bundle Branch Area Pacing

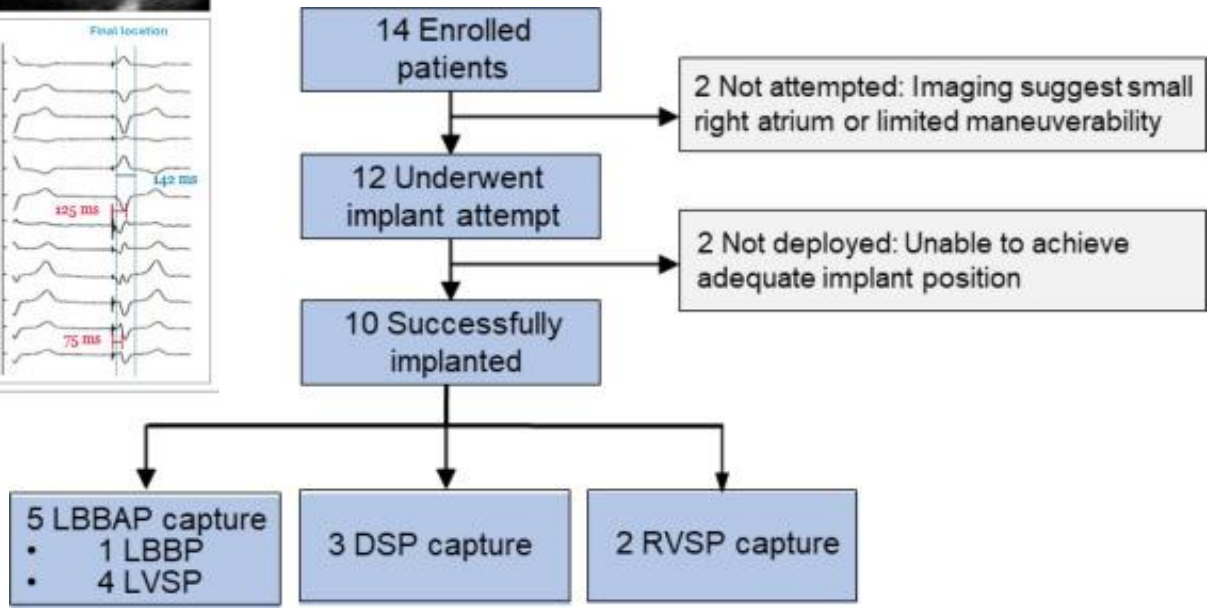
**Reddy V / Nair D / Neuzil P Heart Rhythm 2025**



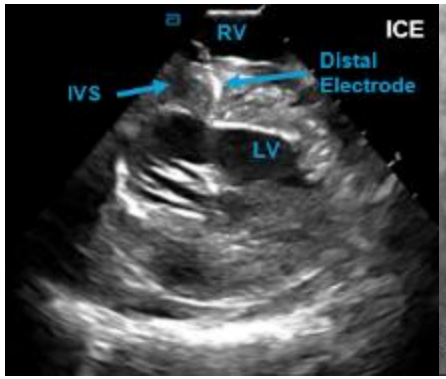

*AVEIR CSP*



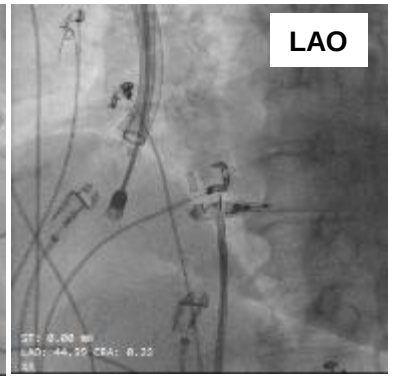


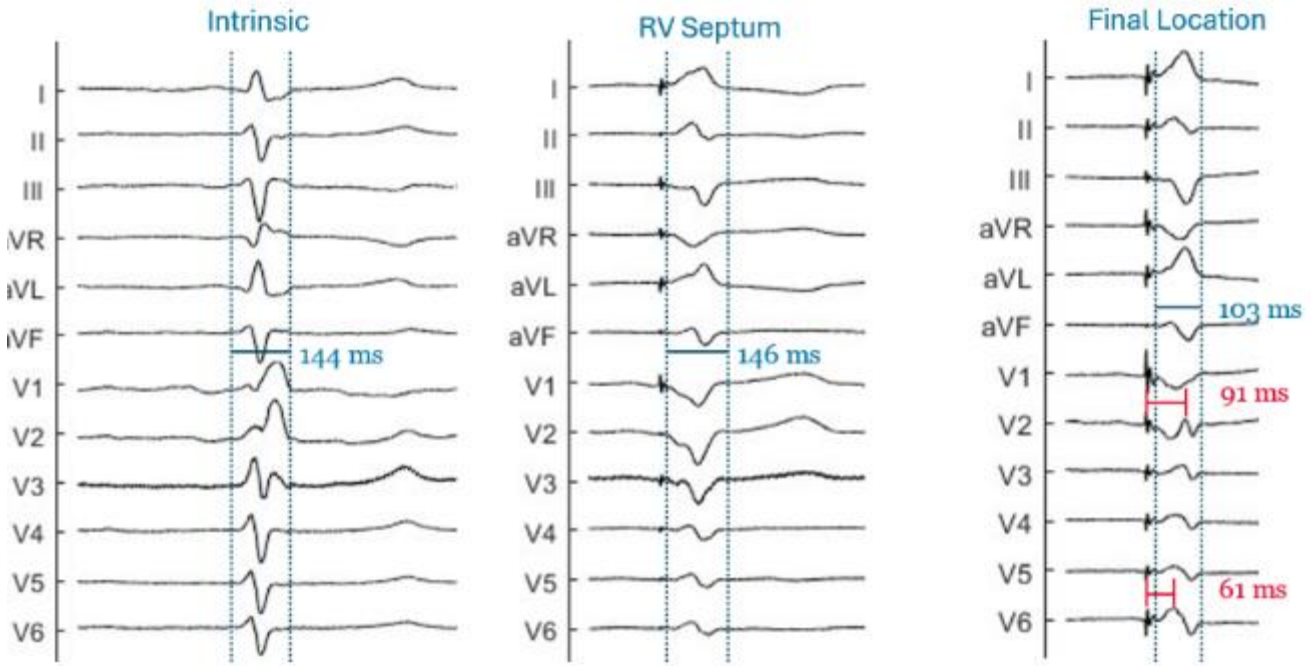
# F-I-M Study of a Leadless Pacemaker System for Left Bundle Branch Area Pacing

- 74 yo, Female, RBBB, SND, History of AF
- Capture type Assessment
  - Electrode tip on the left side of septum
  - V6 RWPT of 61 ms
  - **V6-V1= 30 ms**
  - **Terminal r wave visible in V2**
- Capture type: **DSP**





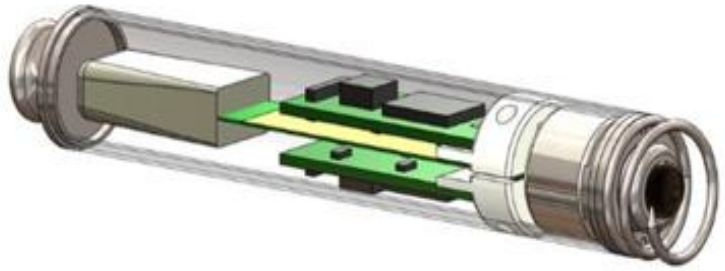


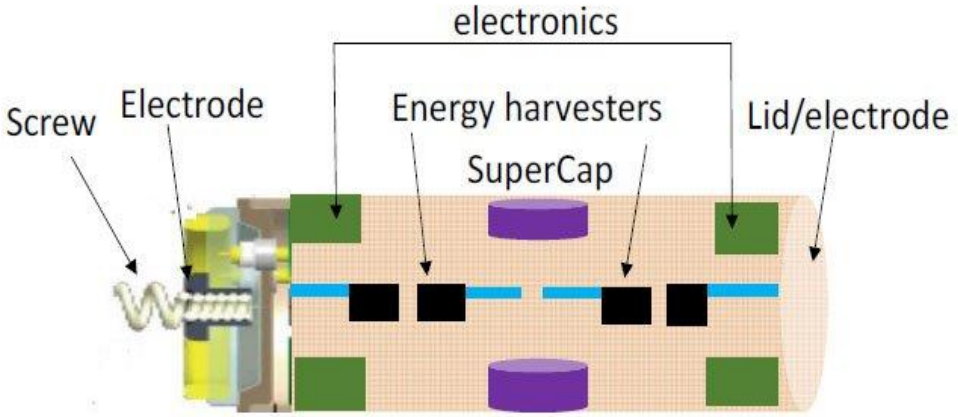



# Nová technologie baterií

## *„harvesting“ energie*

- Kardiokinetika jako zdroj energie pro stimulaci:






[Piezoelectric energy harvester for pacemaker application: a comparative study - IOPscience]

| 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 | Beat to beat capture verification |
| | | Automatic sensing adaptation |
| | | Holter episode for EGM + Acceleration |
| | | Daily/weekly Home-monitor transmission |

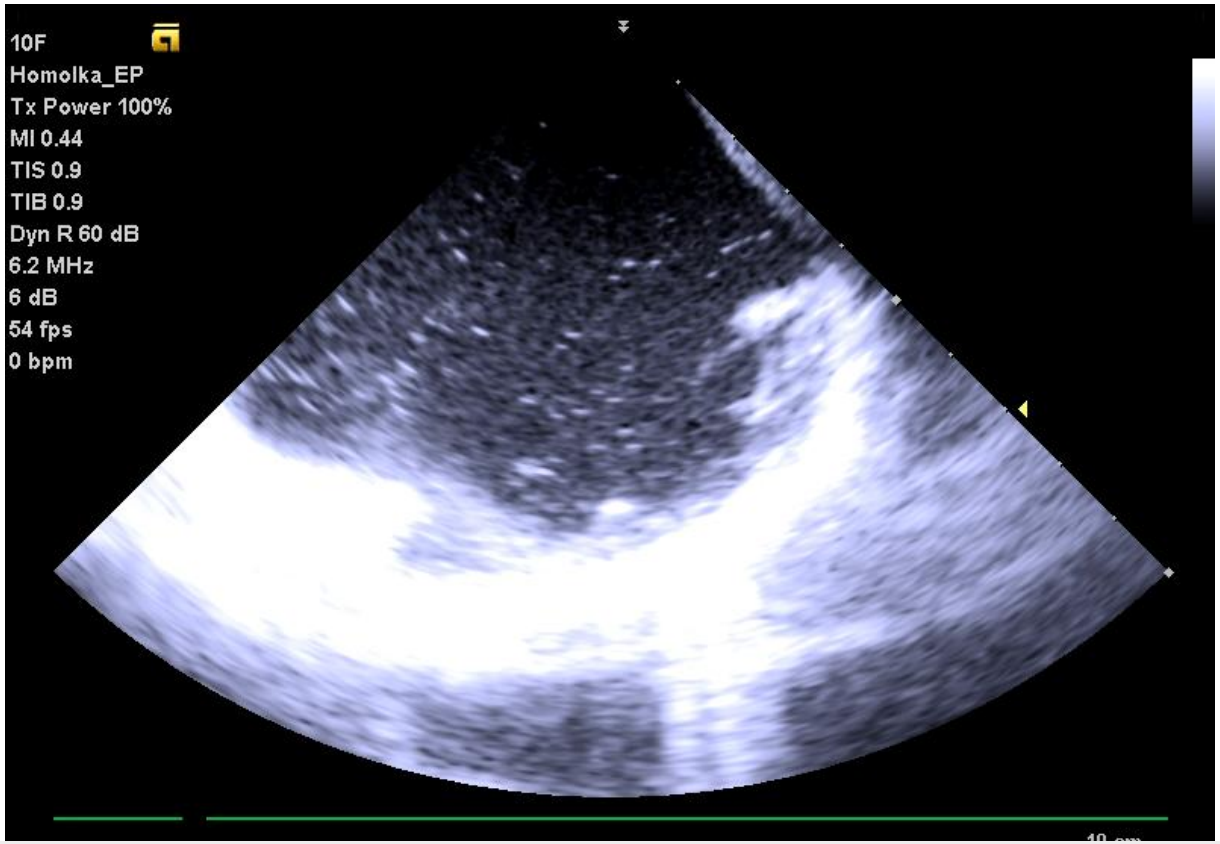
# SILNÝ LEADLESS

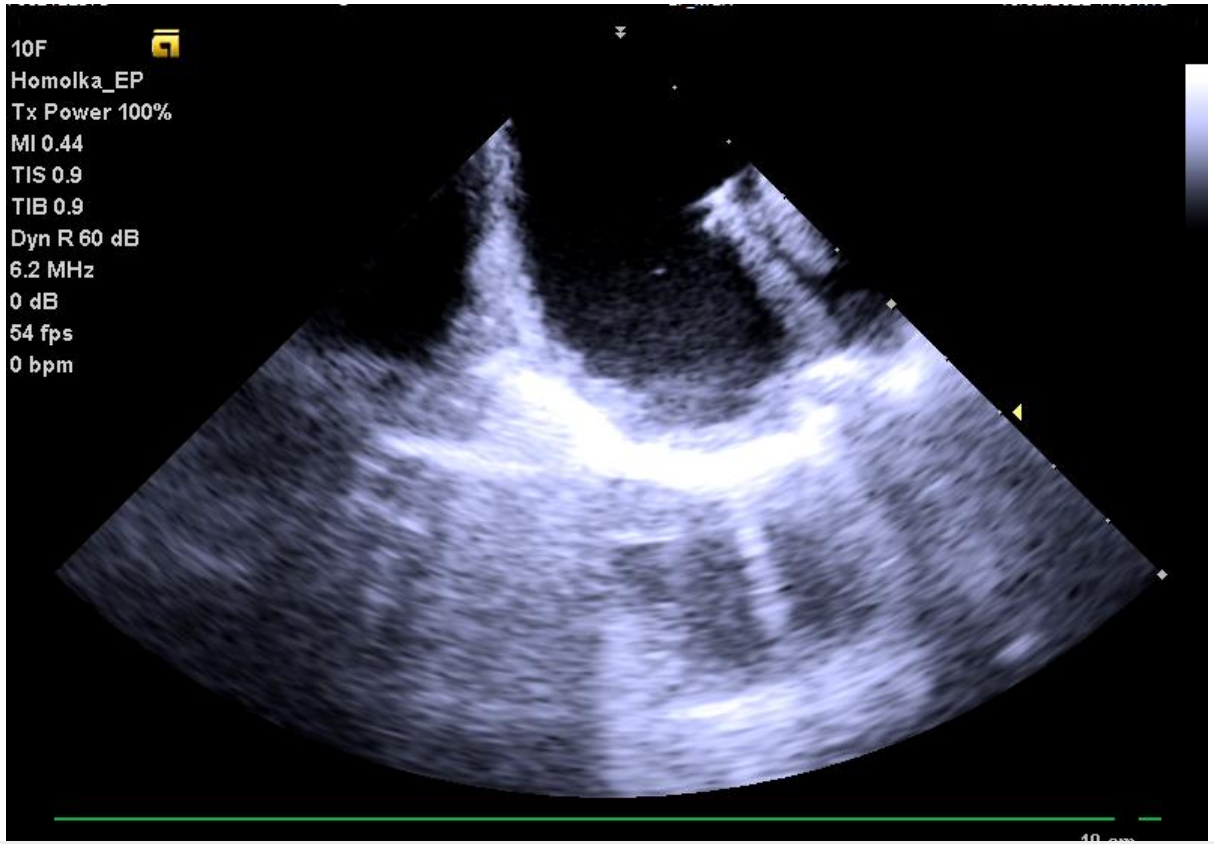

# SLABÝ TRANSVENOUS

# TAK KDO MŮŽE BÝT PROTI??

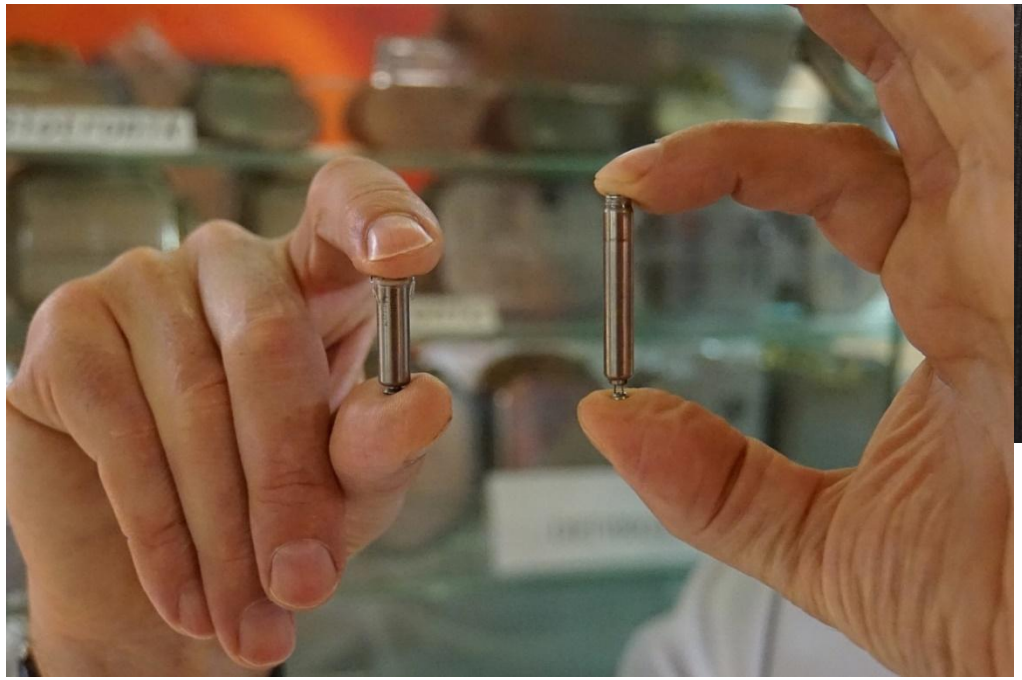
# Dvoudutinový leadless Aveir DR

*implantace síňového Aveir - ICE*



# 13 LET PO PRVNÍ IMPLANTACI
# NENÍ
# LEADLESS KARDIOSTIMULACE
# SVÉBYTNOU PLATFORMOU



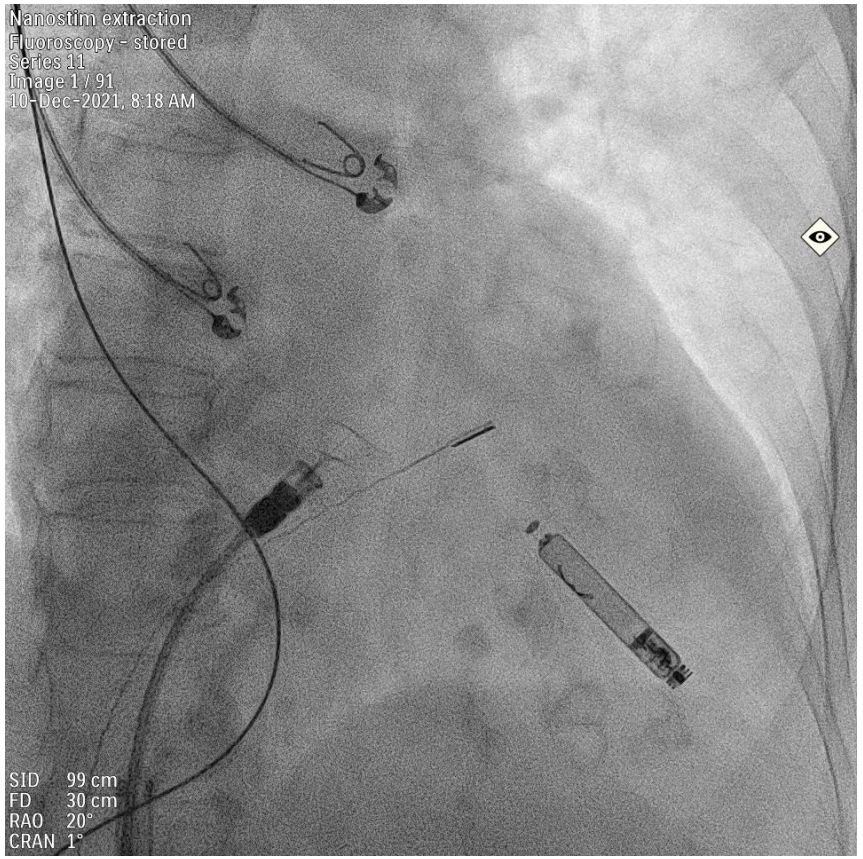


Reddy V/Knops R/Sperzel J/Neuzil P Circul 2014 129;1466-71

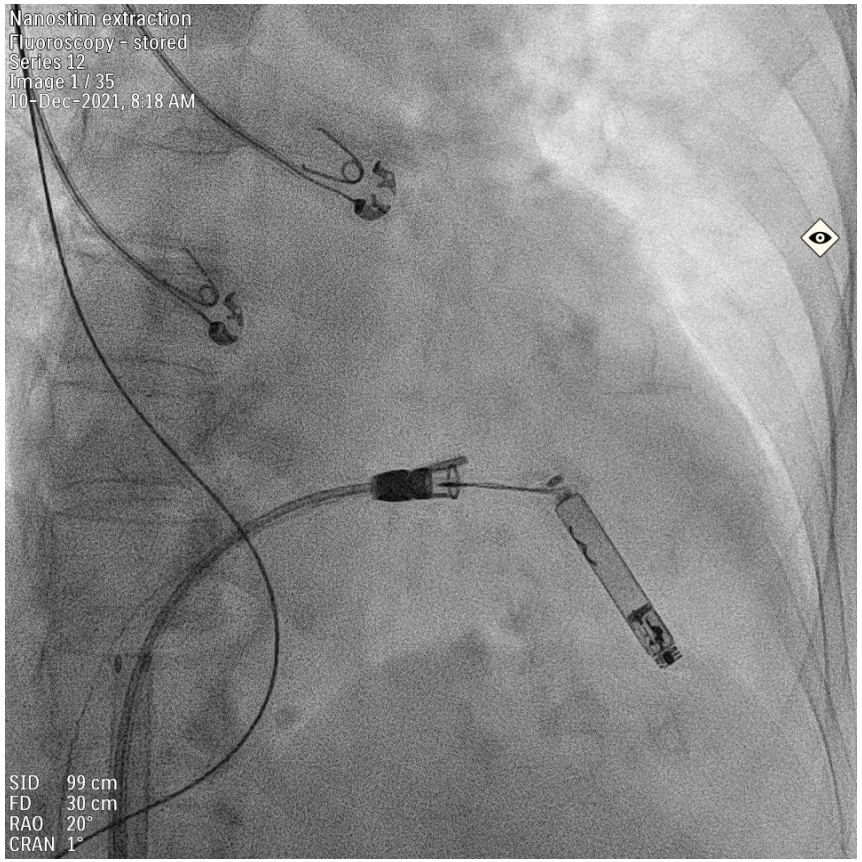
# Case report

*Nanostim LCP retrieval December 10,2021*

**Tri-Loop High Torque retrieval catheter**
**CAPTURE Dec 10, 08:18**




**Tri-Loop High Torque retrieval catheter**
**DOCKING Dec 10, 08:18**

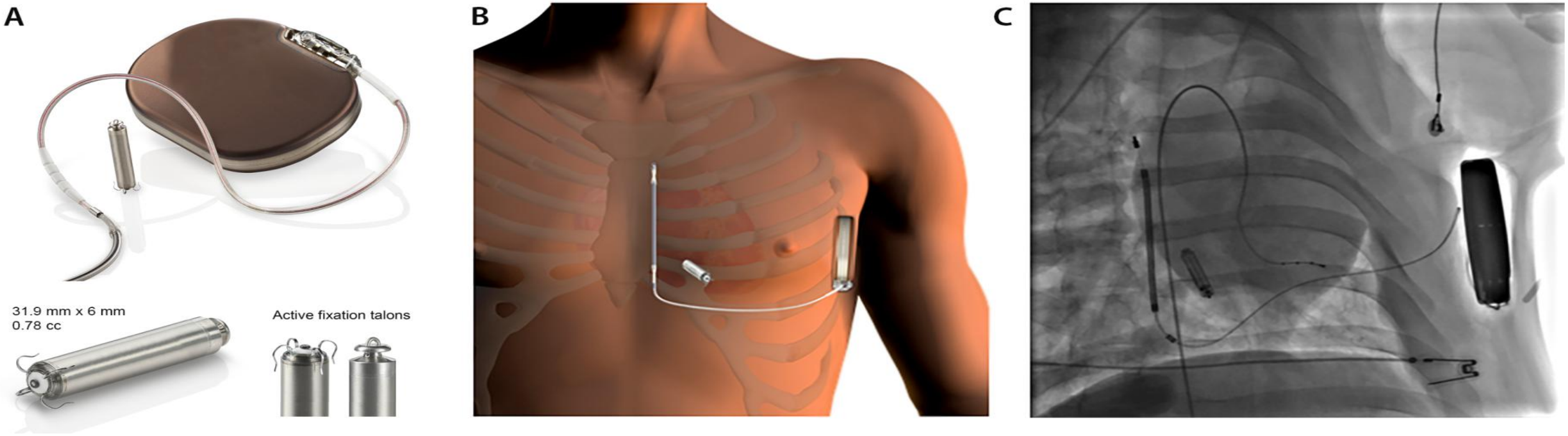



**Neuzil P et al***: HeartRhythm Case Rep. 2023 Feb 3;9(4):258-262*

# Komunikace Leadless ATP & S-ICD:

## *Preklinický model*

Koncept: Leadless Systém umožňuje brady pacing, ATP a defibrilaci




*Tjong F.V.Y. et. al., JACC:2020*

# 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***

# 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**

  **Klinická studie: MODULAR ATP**

# Komunikace Leadless ATP & S-ICD:

*Kazuistika*

## SUMMARY REPORT

Boston Scientific

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

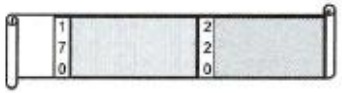
Patient Name: 0492MA555
Last Follow-up Date: 12/19/2023
Follow-up Date: 01/02/2024
Implant Date: 01/25/2022

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

### Programmable Parameters

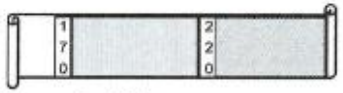
**Current Device Settings**
Therapy: ON
Shock Zone: 220 bpm (ATP On)
Conditional Shock Zone: 170 bpm (ATP x2)
Post Shock Pacing: OFF
SMART Pass: OFF

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**

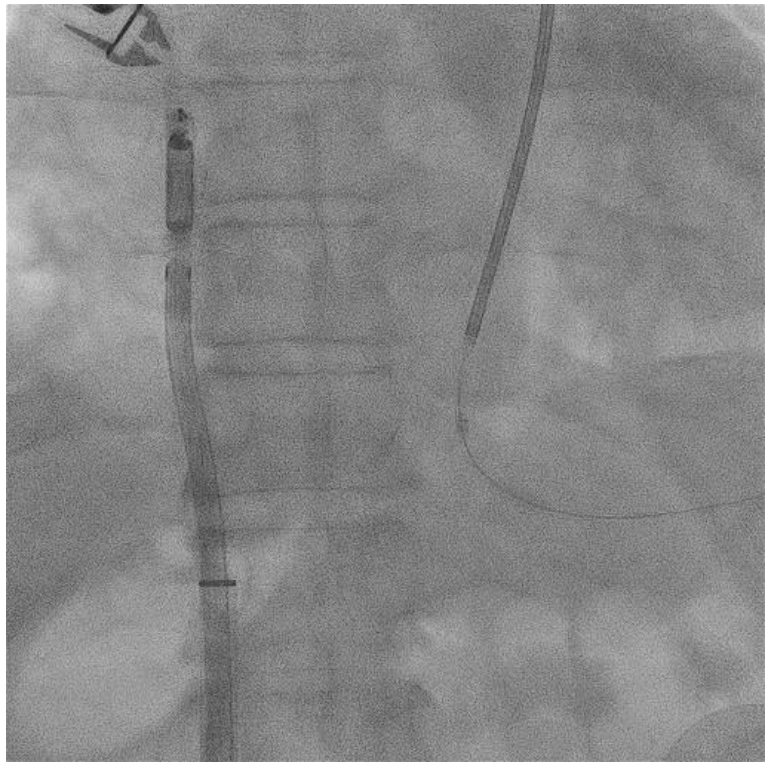
Remaining Battery Life to ERI: 43%

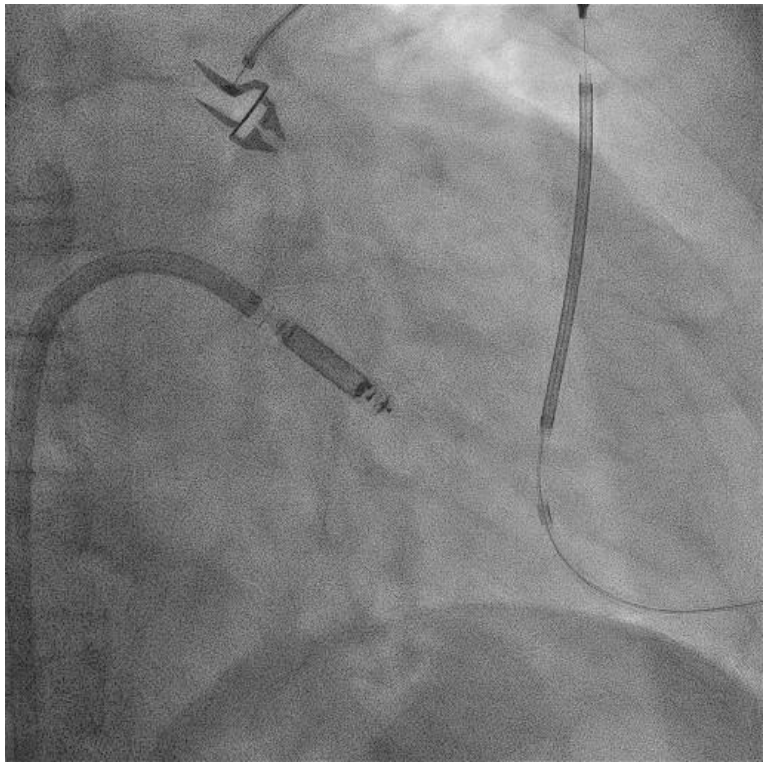
**Electrode Impedance Status**

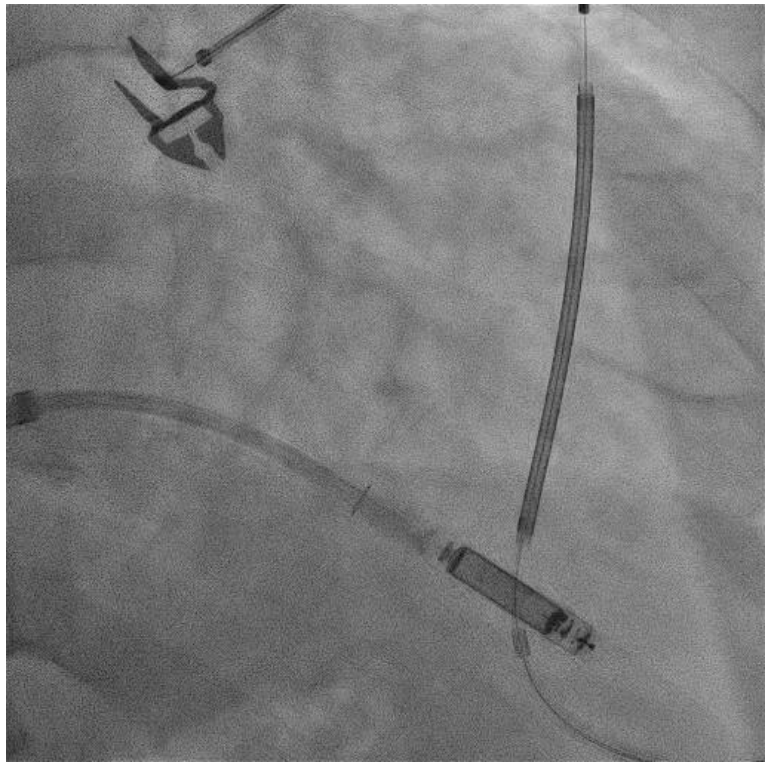
⚠ System Impedance = 210 Ohms

# Komunikace Leadless ATP & S-ICD:

## *Kazuistika*

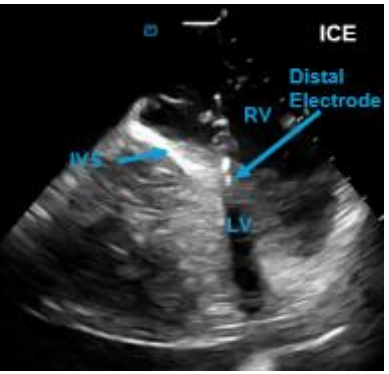


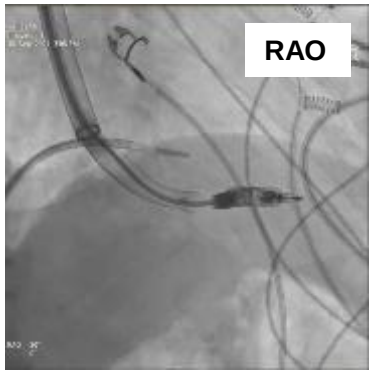


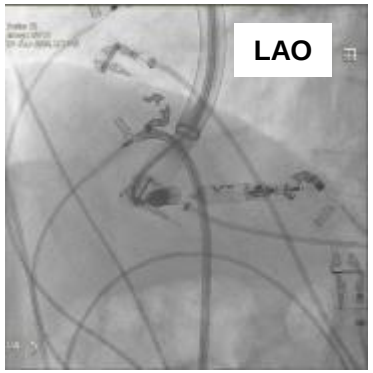


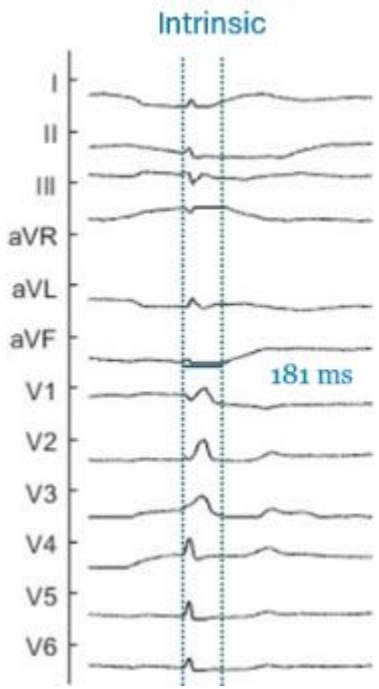
# F-I-M Study of a Leadless Pacemaker System for Left Bundle Branch Area Pacing

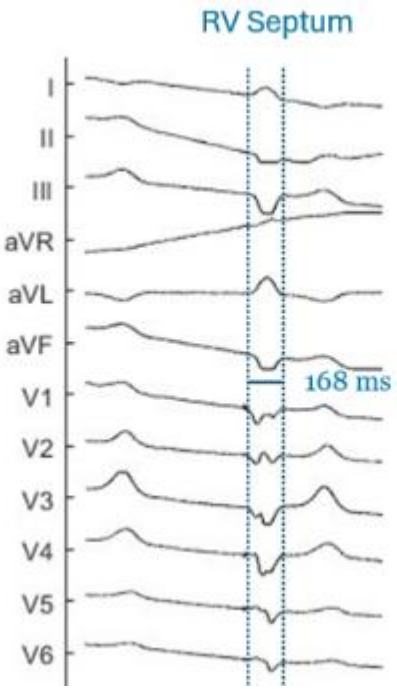
- 77 yo, Male, RBBB, SND, CHF, NYHF Class II
- Capture type Assessment
  - Electrode tip on the left side of septum
  - V6 RWPT of 75 ms
  - V6-V1= 50 ms
  - **Small Terminal r wave visible in V1**
- Capture type: **LVSP**

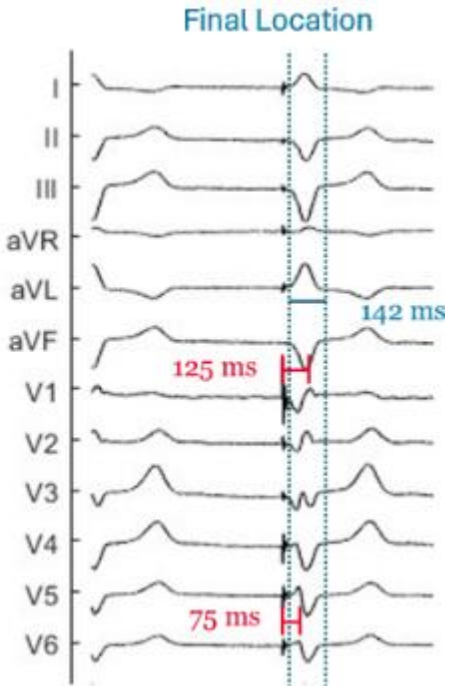


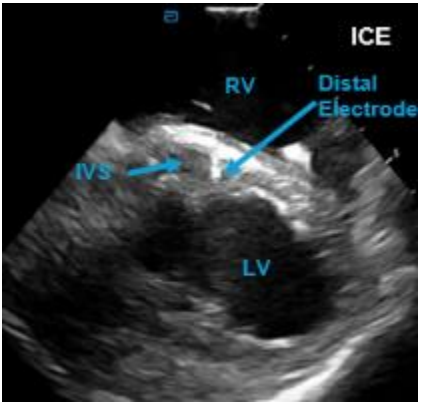



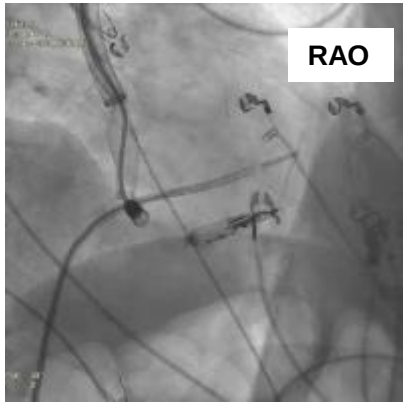



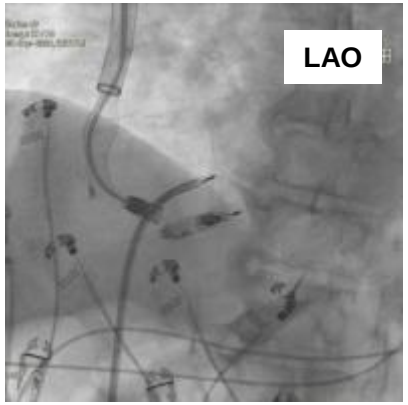



# F-I-M Study of a Leadless Pacemaker System for Left Bundle Branch Area Pacing

- 74 yo, Male, SND, History of AF, CAD, and PCI
- Capture type Assessment
  - Electrode tip on the left side of septum
  - V6 RWPT of 75 ms
  - V6-V1= 54 ms
  - Terminal r wave visible in V1
- Capture type: **LBBP**




Red denotes Stim to RWPT on V1 and V6
Blue denotes QRS duration measured from onset to offset