Nový impulz léčby srdečních arytmií

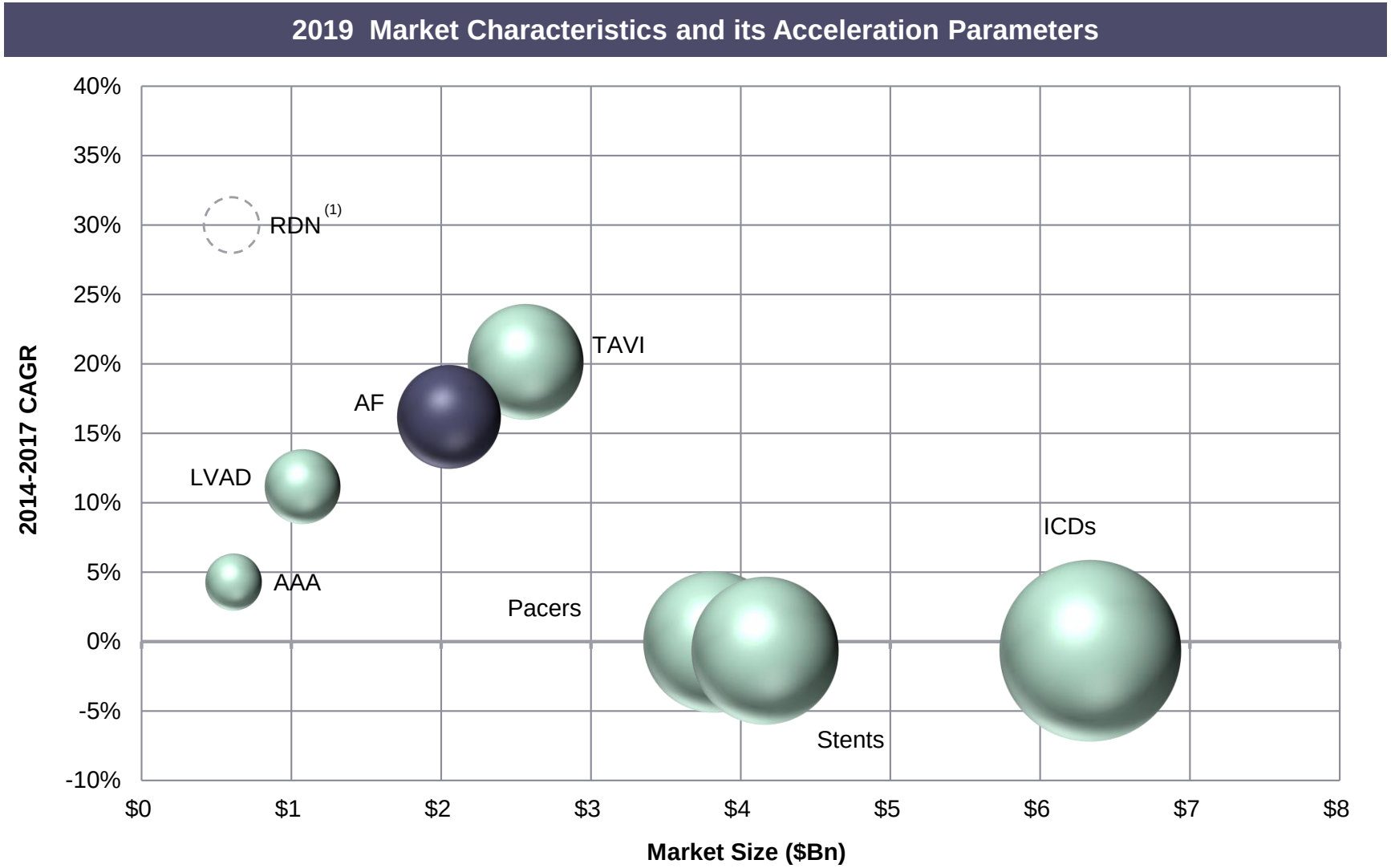
AFFERA

Petr Neužil

Heart Center & Cardiology Department 1.LF UK a FNMH, Prague

pneuzil@seznam.cz

Atrial Fibrillation is One the Fastest Growing - Up Markets in Cardiology



Management Estimates, J.P. Morgan Market Models, Credit Suisse Research Models : Market Prediction for 2019

Atrial Fibrillation – prediction uf US market

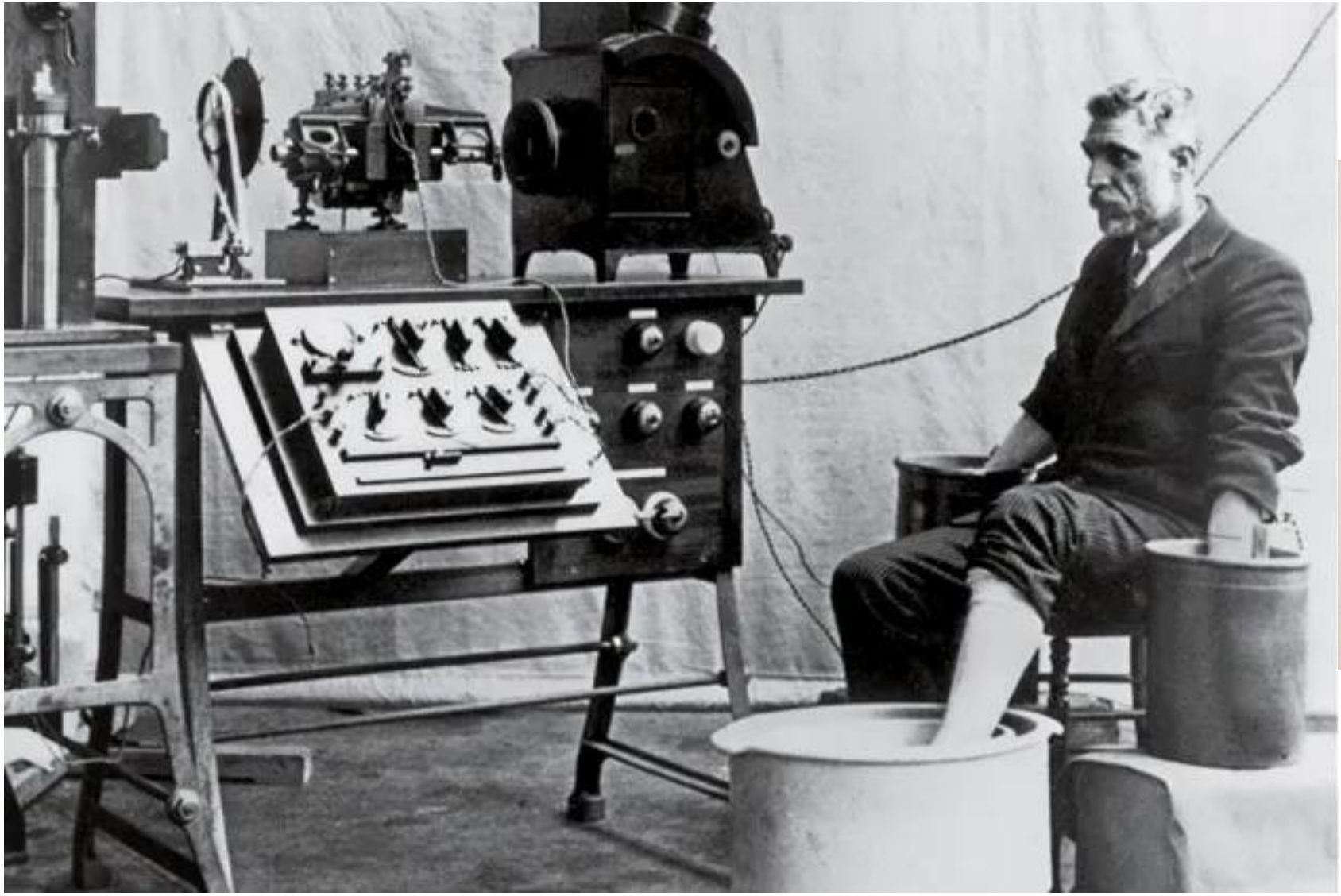
- ***Multiple risks***
- ***The most common arrhythmia with increasing incidence dependent on aging & „lifestyle“ disease***

  - 3 milions of US citizens has evidence of AF
  - 2050 (estimated) ~ 15 milions of US citizens
  - prevalence 2- 3 %; estimate growth for 5% in 2050
  - aging of population increases its incidence up to 15% > 75 years
  - ↑ risks of concomitant diseases *AF increases risk of stroke 7x and cardiovascular events 2x*
  - Medicare: > 1.7 milion of hospital admissions / year
  - 560.000 patients treated in US (2024)
  - Catheter ablation is a first line therapy for AF

  - **Total amount of health care expences for patients with AF:**

$ 26 billion / 2024 with 20% + growth

Willem Einthoven First ECG



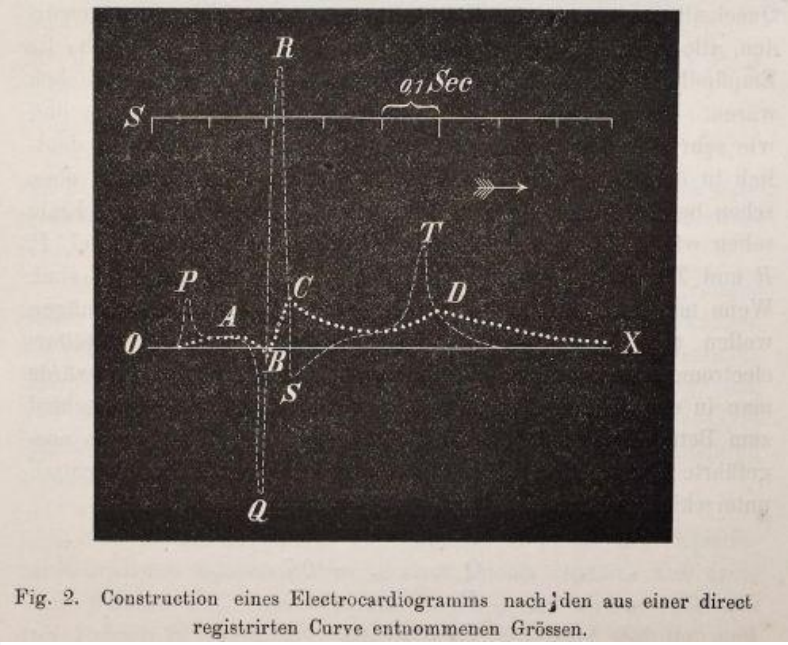
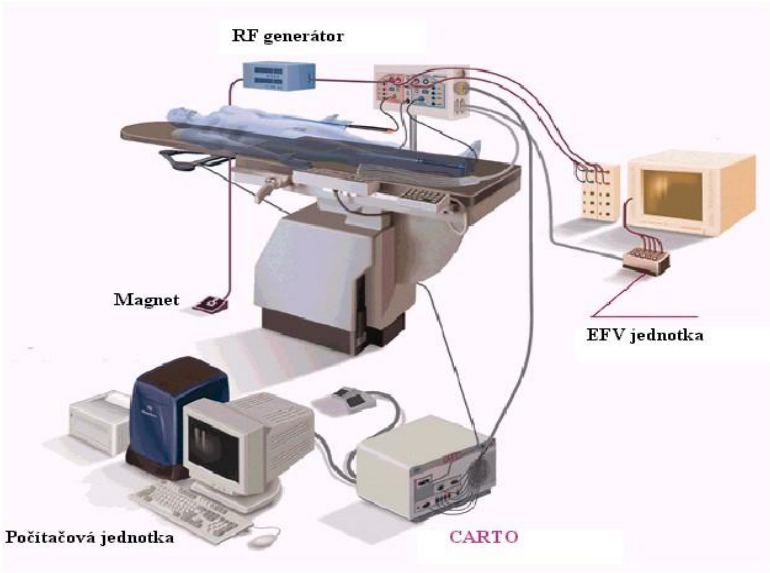
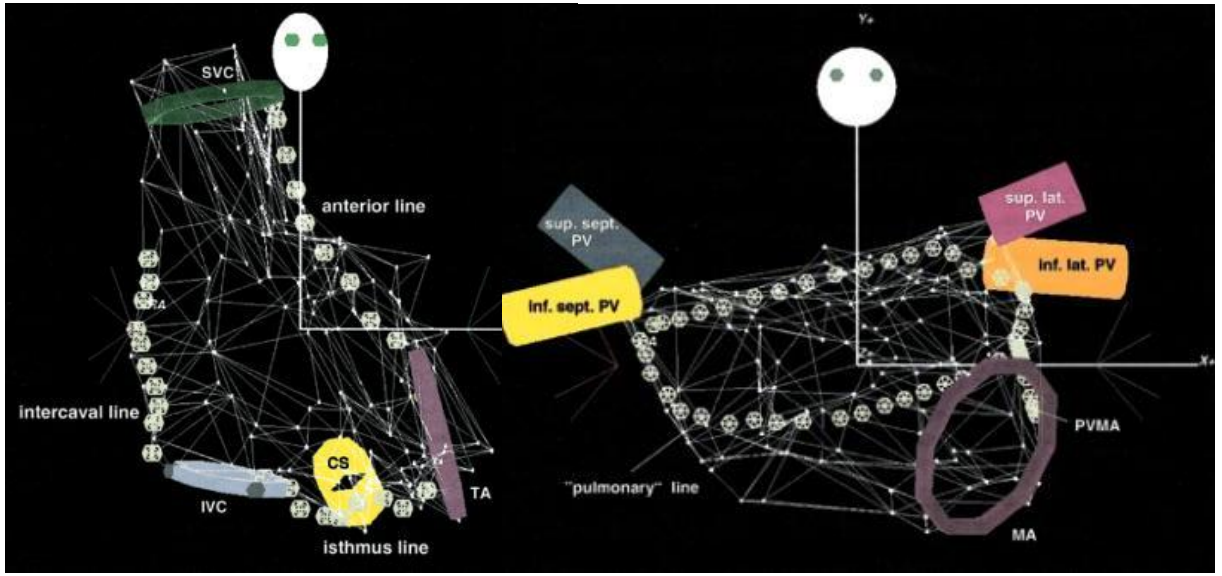


Fig. 2. Construction eines Electrocardiogramms nach den aus einer direct registrirten Curve entnommenen Grössen.

Development of First Mapping Systems
CARTO & LocaLisa

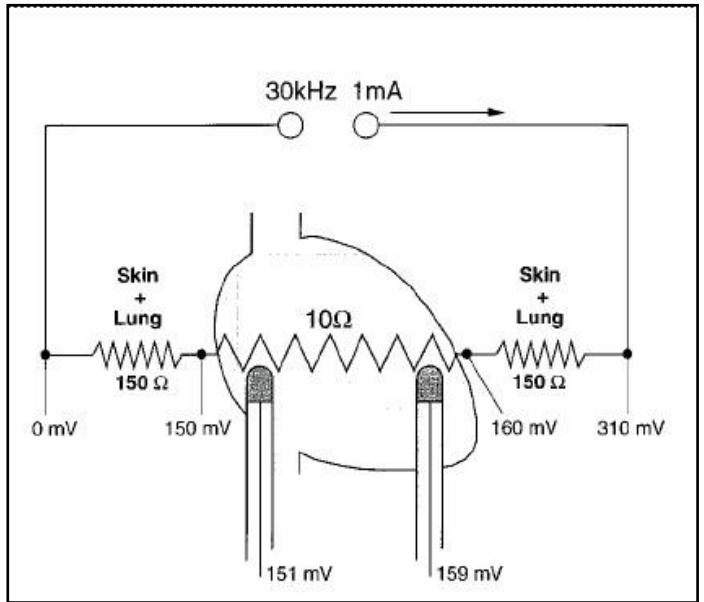


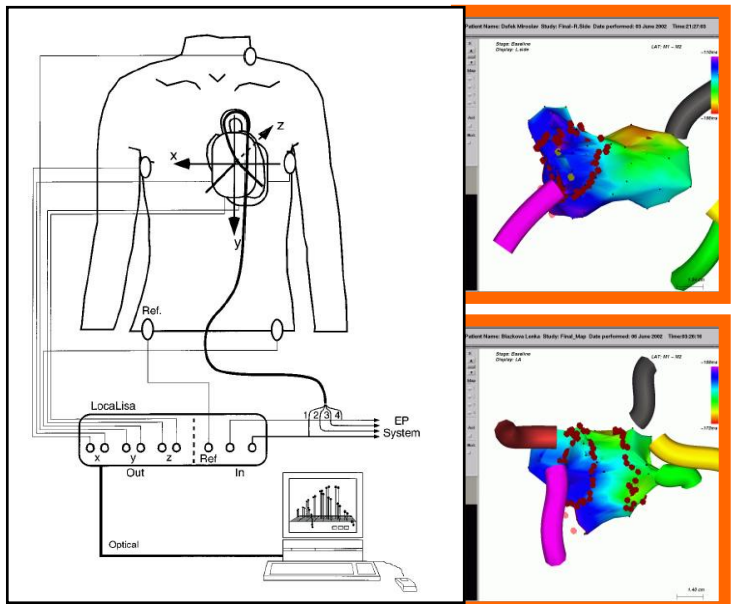


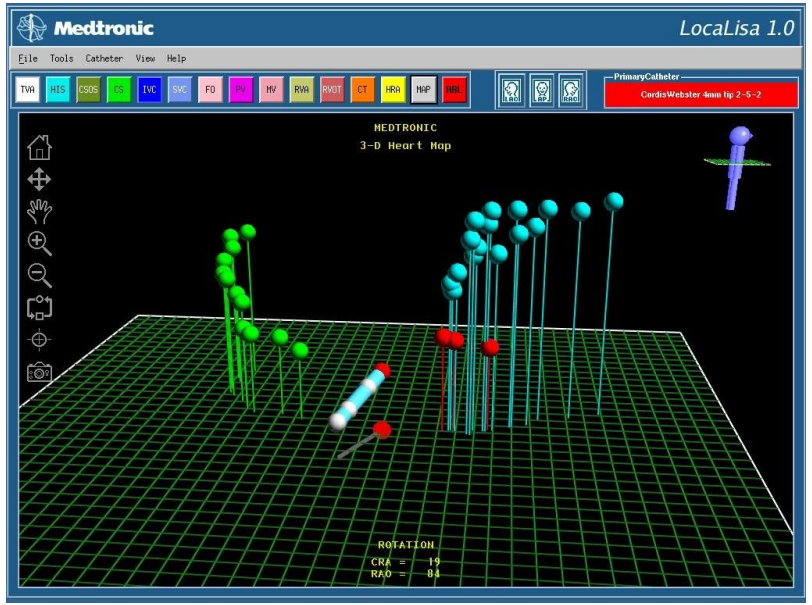
45 pts, LA:7.9+/-1.4 h.
PA: 6.6+/-2.0 h.
100% recurrences

LA: 0 complete lines
CTI only

S Ernst, Circulation, 1999

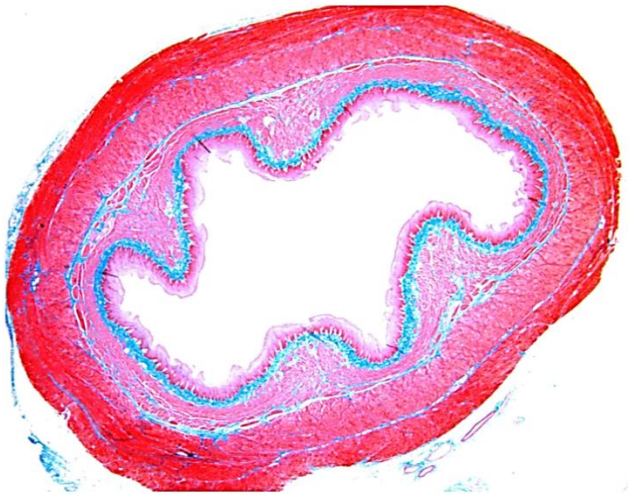


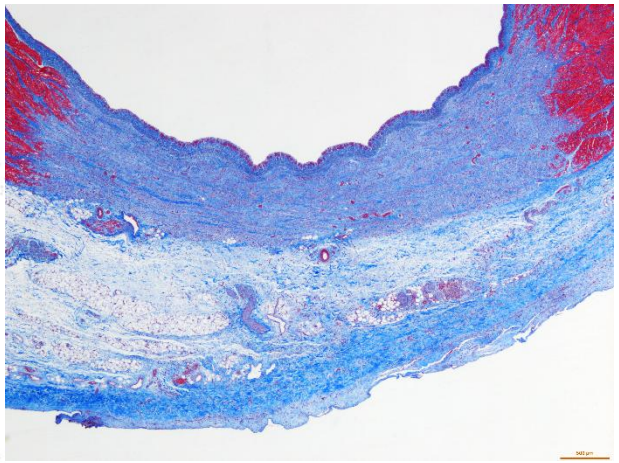


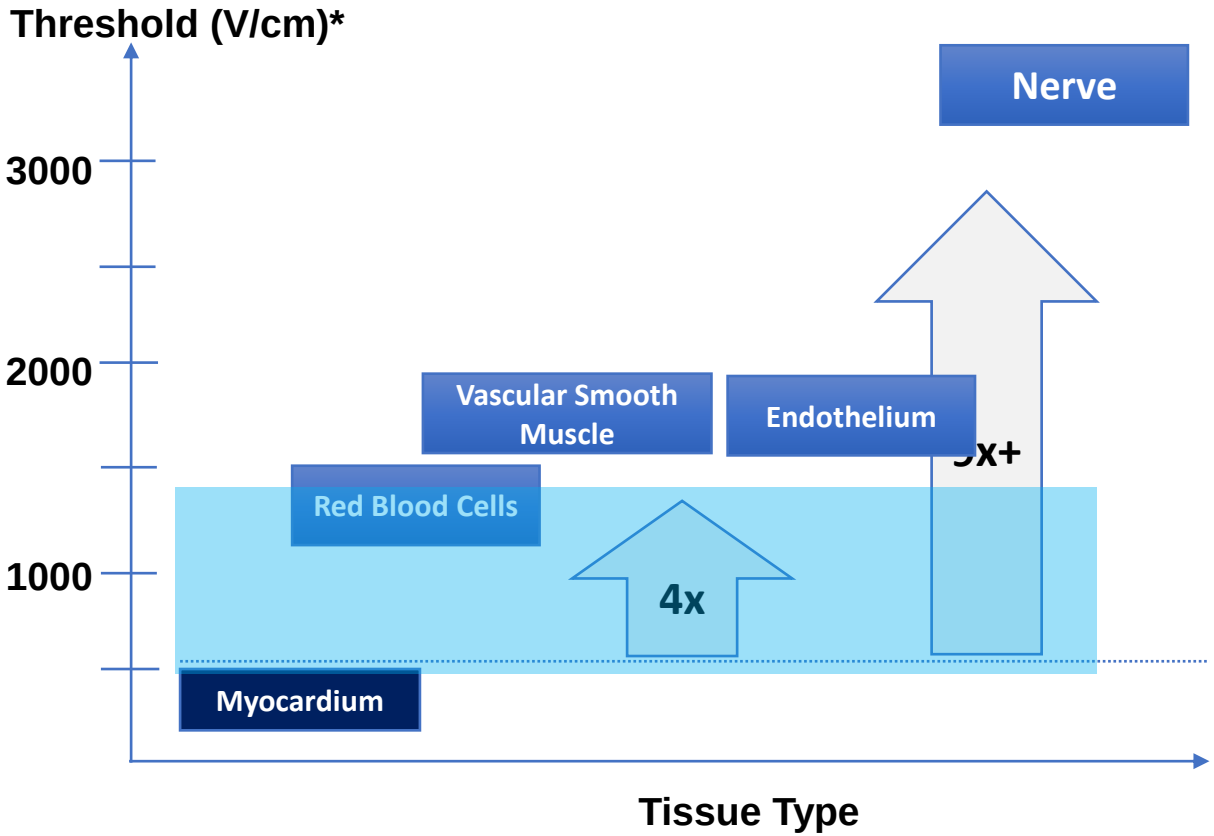


Pulsed Field Ablation

Tissue "Selectivity"



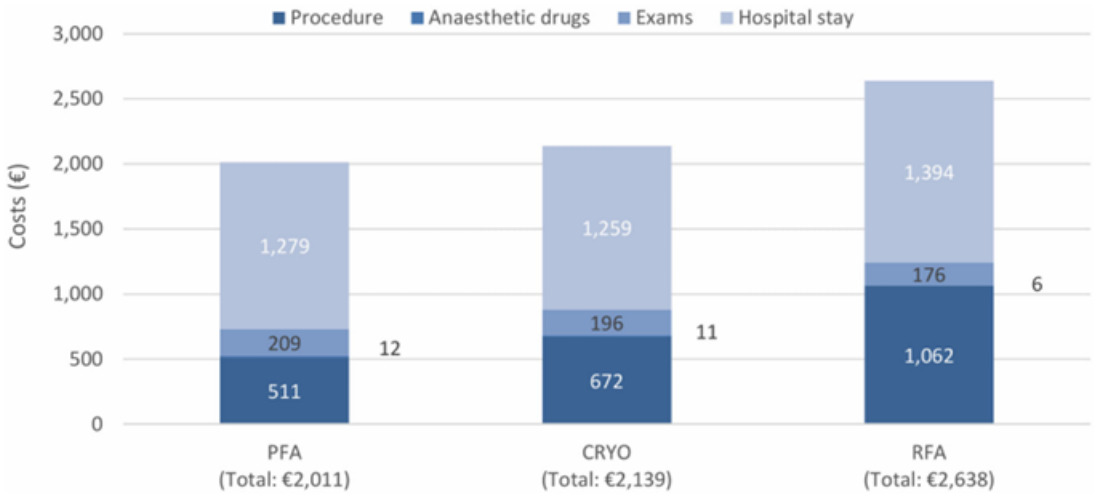


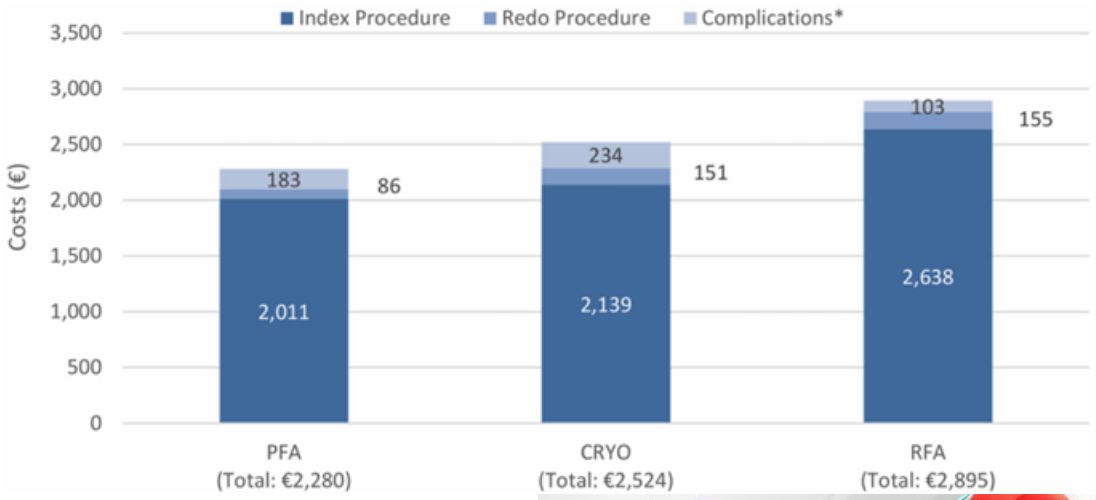


Wittkampf FH, Van Driel VJ, Van Wessel H, et al., *JCE* 22:302–309 (2011)
van Driel VJ, Neven KG, van Wessel H, et al. *Circ EP*. 7:734–738 (2014)
Neven K, van Driel V, van Wessel H, et al. *Circ EP*. 7:913–919 (2014)
du Pré BC, van Driel VJ, van Wessel H, et al. *Europace*. 15:144–149 (2012)
Neven K, van Es R, van Driel V, et al. *Circ EP*. 10(2017)
VY.Reddy, J.Koruth, P.Jais et al, *JACC EP* 4:987-995 (2018)

Cost Analysis of Three Ablation Technologies

Time, mean ± SD	PFA (N = 90)	CRYO (N = 100)	RFA (N = 80)	p-value**			
				Overall	PFA vs CRYO	PFA vs RFA	CRYO vs RFA
Procedural time by phase							
Pre-procedure, min	24.56 ± 17.92	27.71 ± 22.80	27.71 ± 10.63	0.4094	0.706	0.784	1.000
Skin-to-skin, min	60.61 ± 21.60	82.21 ± 26.95	152.98 ± 48.97	<0.0001	<0.0001	<0.0001	<0.0001
Post-procedure, min	22.84 ± 13.28	33.20 ± 22.5	23.86 ± 12.05	<0.0001	<0.0001	1.000	<0.0001
Total, min	108.01 ± 36.24	143.12 ± 46.44	204.55 ± 51.17	<0.0001	<0.0001	<0.0001	<0.0001
Professional workload*							
Physician, min	123.87 ± 54.64	165.66 ± 72.48	310.82 ± 123.23	<0.0001	0.003	<0.0001	<0.0001
Nurse, min	181.59 ± 86.77	247.83 ± 177.70	341.71 ± 151.56	<0.0001	0.001	<0.0001	<0.0001
Technician, min	47.47 ± 37.29	58.90 ± 53.92	132.39 ± 85.59	<0.0001	0.592	<0.0001	<0.0001
Anesthesiologist***, min	5.73 ± 28.86	2.90 ± 20.45	17.75 ± 60.46	0.0252	1.000	0.118	0.028
Other°, min	48.04 ± 71.79	38.00 ± 78.64	0.00 ± 0.00	<0.0001	0.828	<0.0001	<0.0001
Total, min	406.70 ± 165.44	513.29 ± 196.06	802.68 ± 294.27	<0.0001	0.003	<0.0001	<0.0001



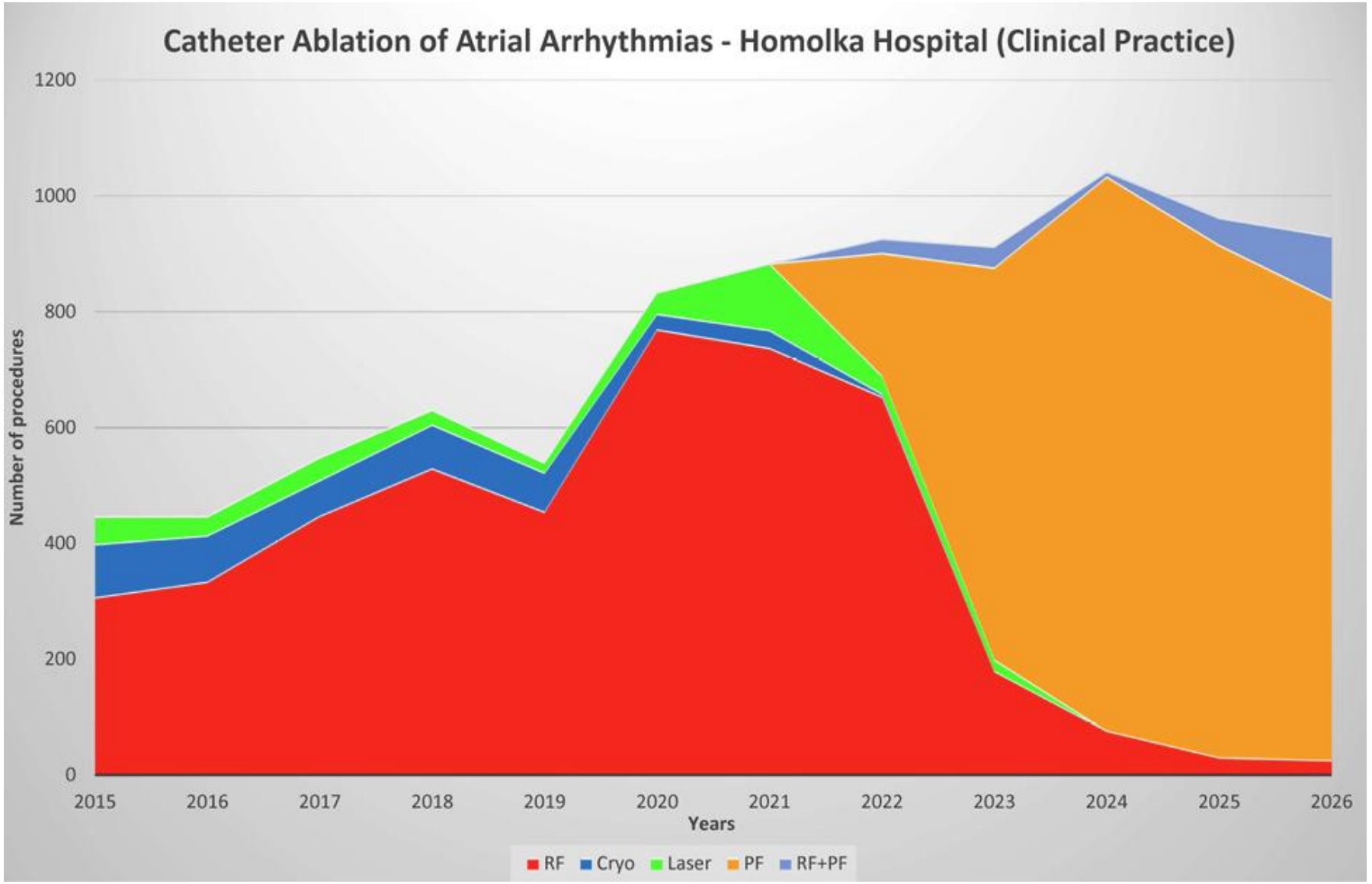


Neuzil et al. *J. Medical Economics* 28, (2025)

XXXIV. VÝROČNÍ SJEZD ČESKÉ KARDIOLOGICKÉ SPOLEČNOSTI

New Technology Adoption

AFib Catheter Ablation in Homolka Hospital – Clinical Practise Only



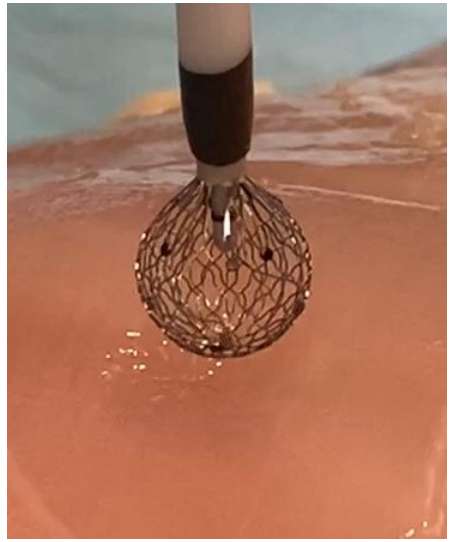
Lattice-Tip RF Ablation Catheter

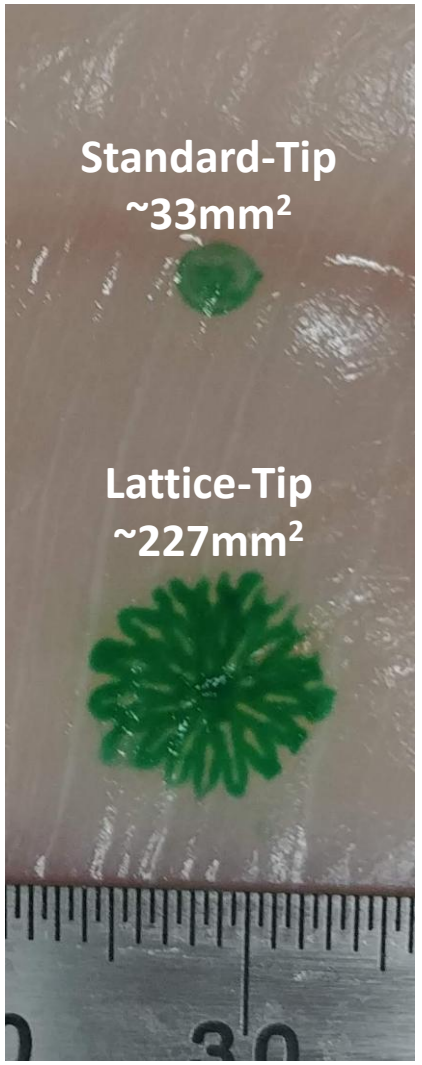
The „First in Man“ Series

- Lattice tip – 9mm diameter
- Nine nodes on surface:
  - Mini-electrodes
  - Surface Thermocouples
- RF Energy from complete tip
- Irrigation from central nozzle
- Integrated Mapping System

Temp-Controlled Ablation

- Atrial Lesions: 2.5 – 5 s
- Ventricular Lesions: 30 – 60 s



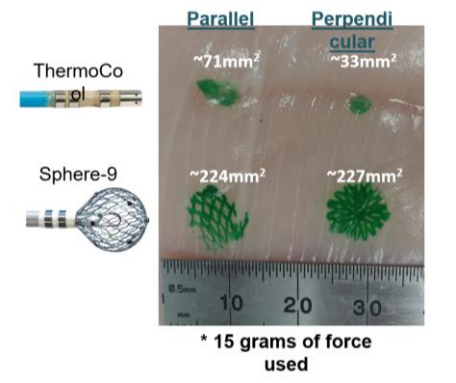


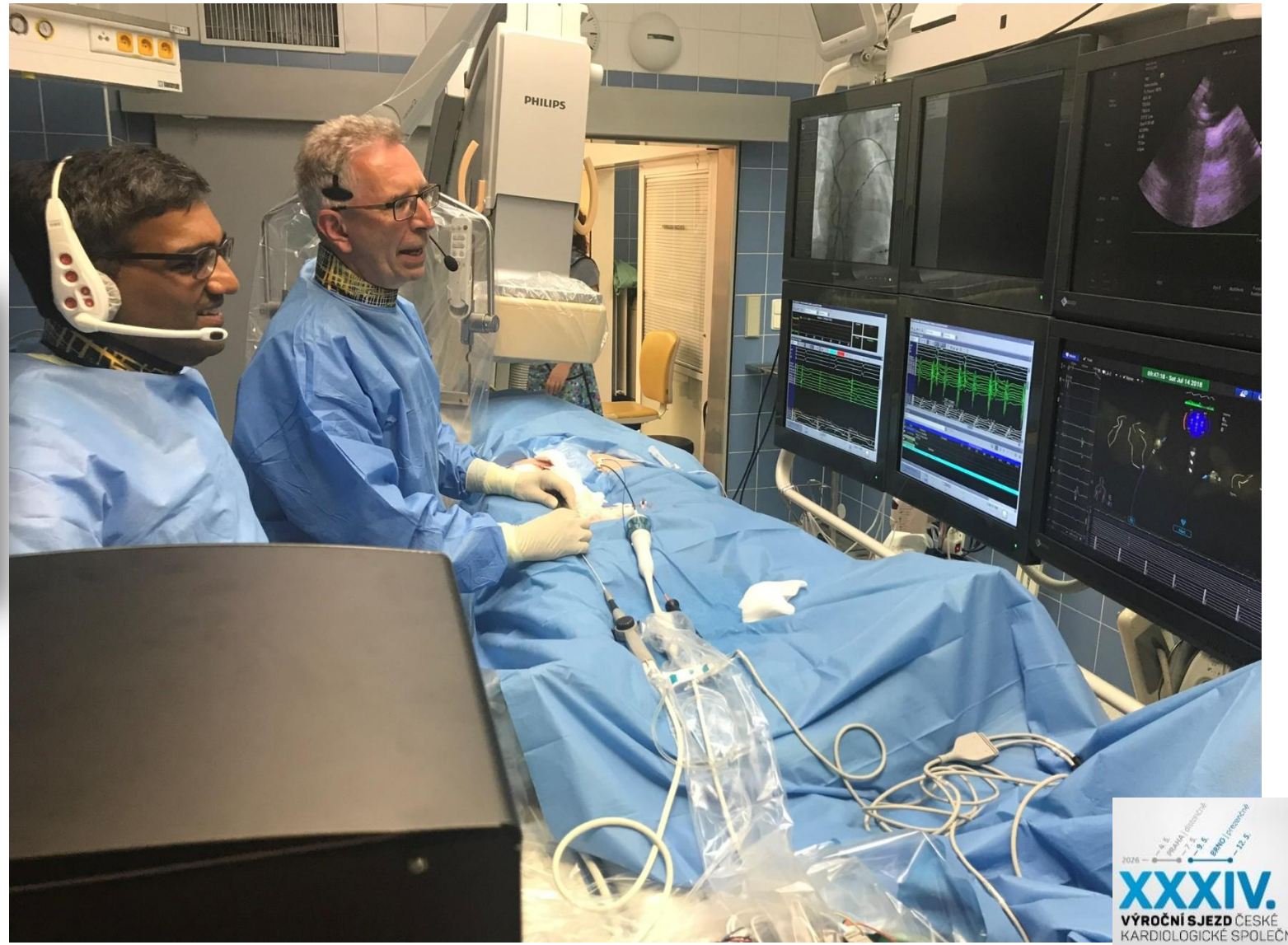
Force = 15 g

Lattice-Tip RF Ablation Catheter

The „First in Man“ Series

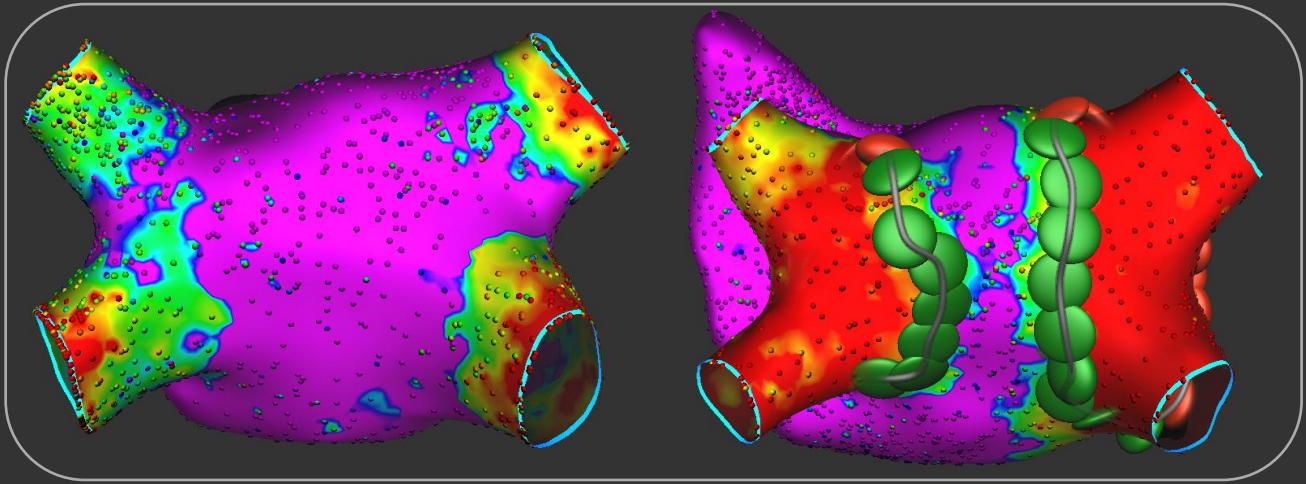
14.7. 2018

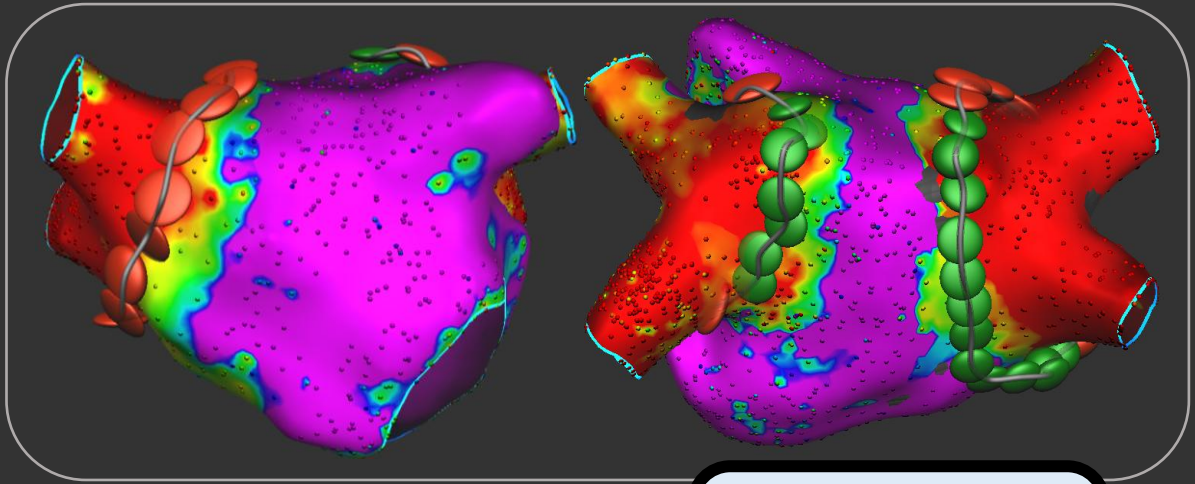




XXXIV. VÝROČNÍ SJEZD ČESKÉ KARDIOLOGICKÉ SPOLEČNOSTI

Post-RF/PF Ablation Mapping

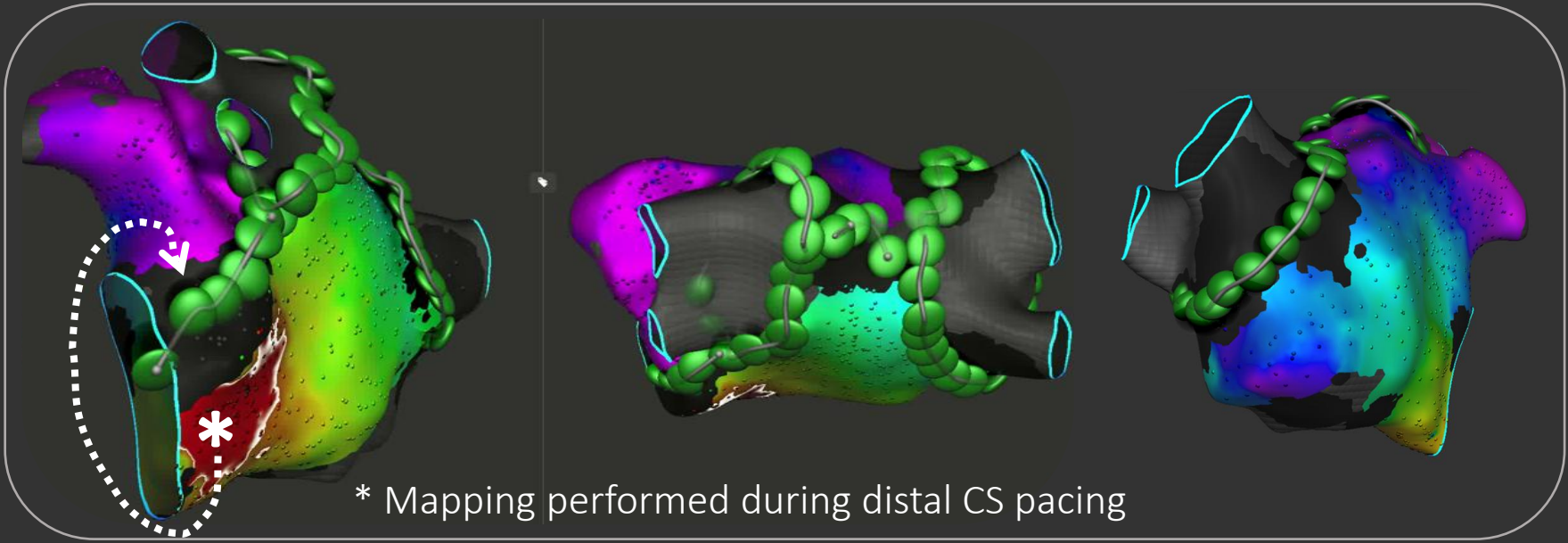




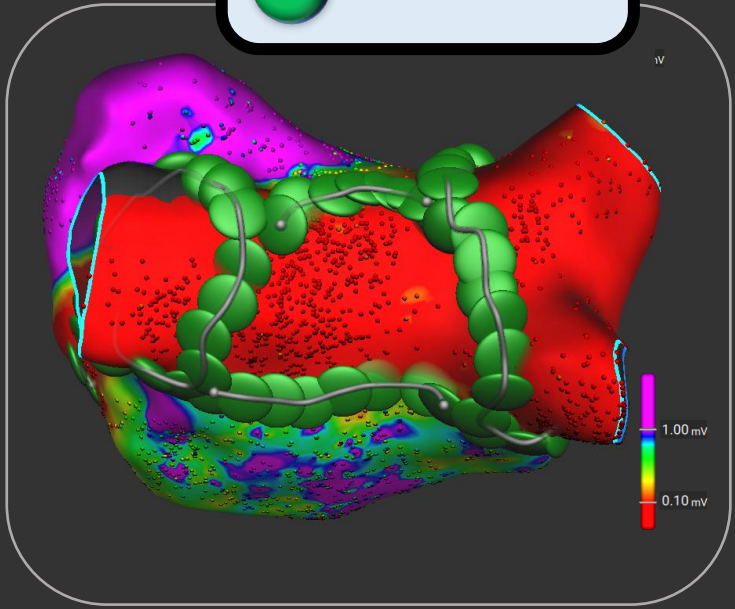
= RF Lesion

= PF Lesion

Post-PF/PF Ablation Mapping

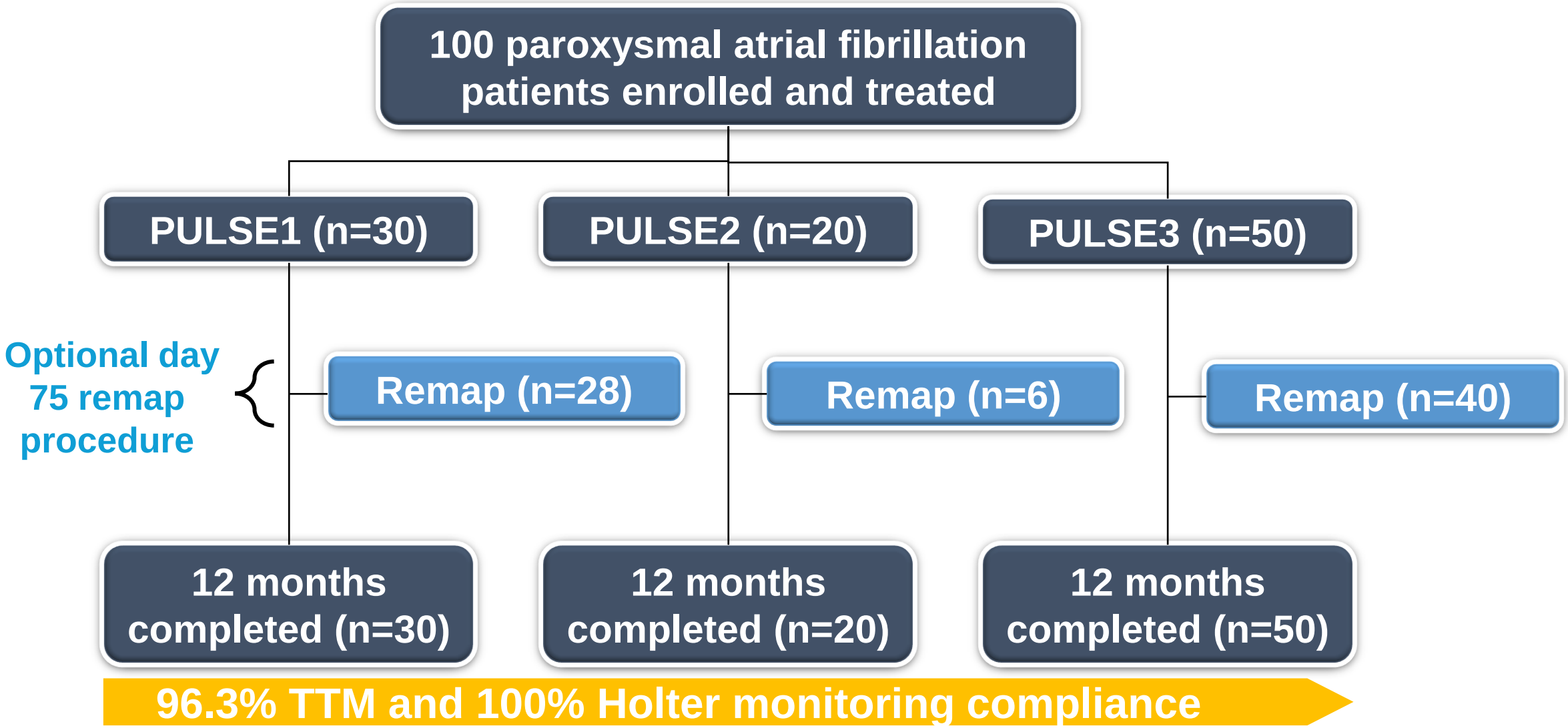


* Mapping performed during distal CS pacing



FIH Clinical Trial

Subject Flow

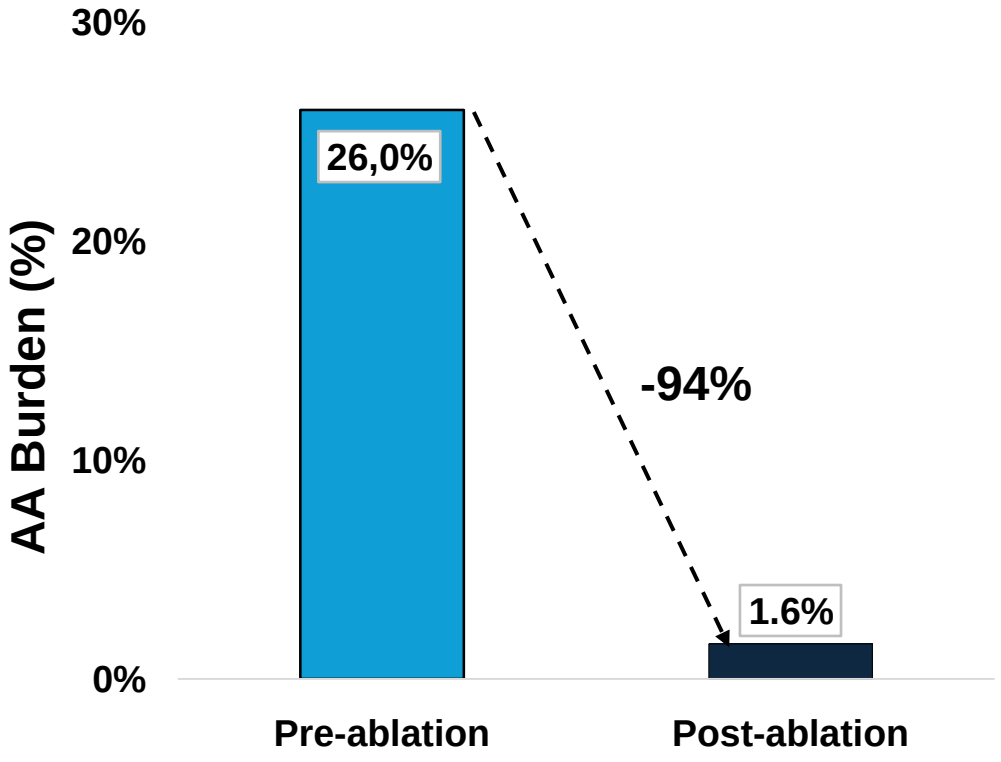


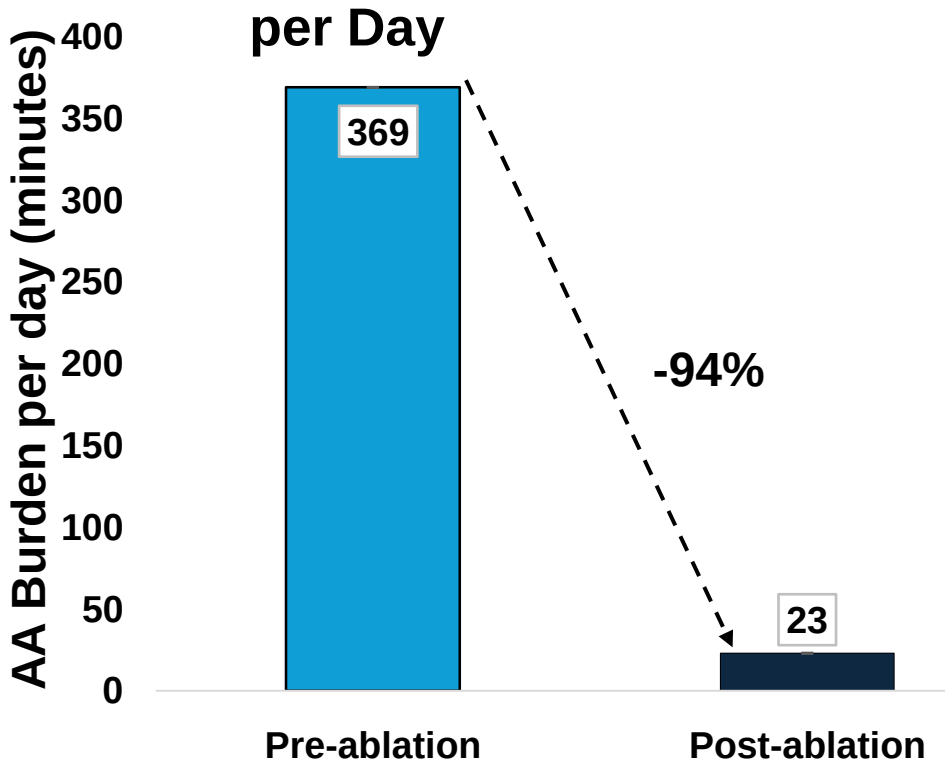
V.Y.Reddy al: JACC EP 2023

Pulse 3 ILR Substrudy (n=15)

AA burden in ILR Sub-cohort with Recurrence

PULSE3 ILR sub-cohort **(n=15)** → with recurrence **(n=3)**



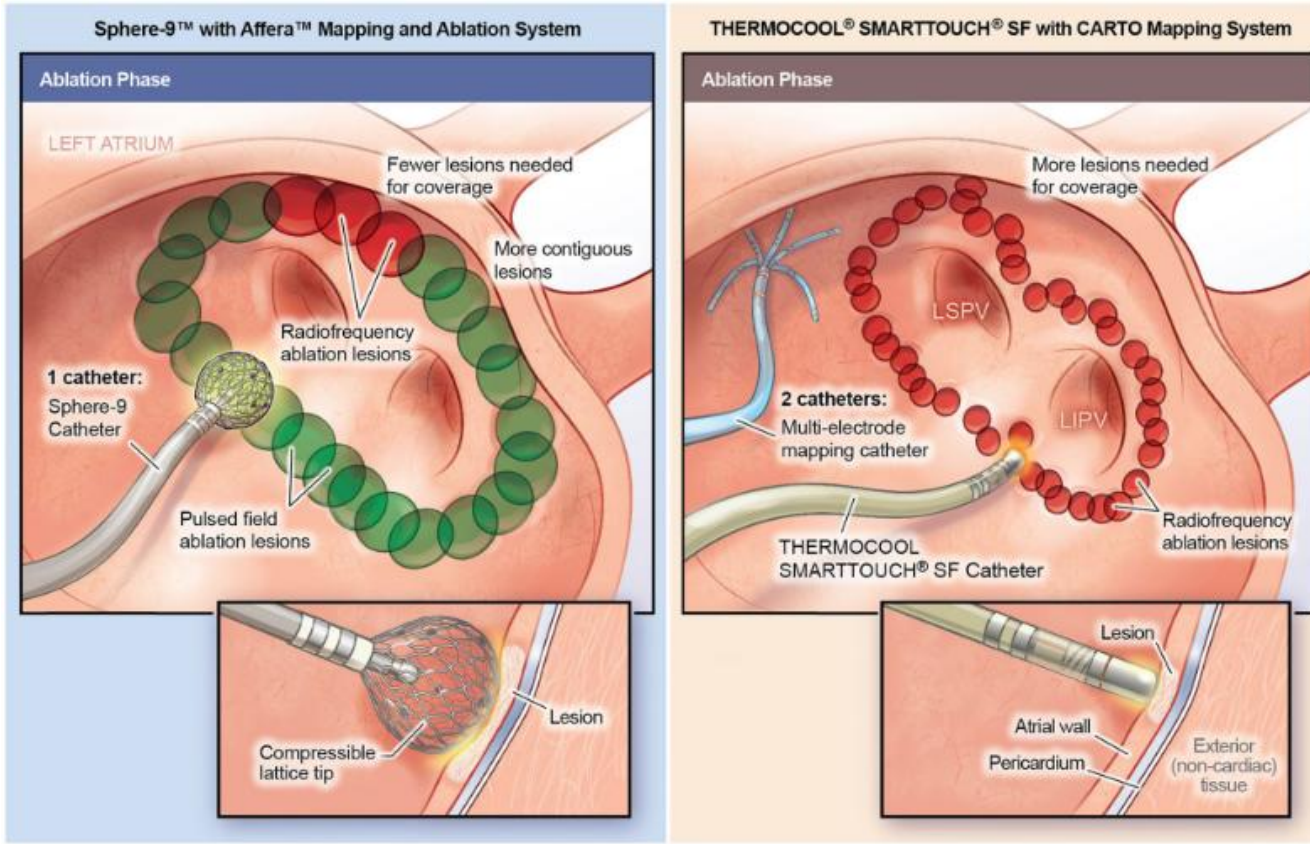


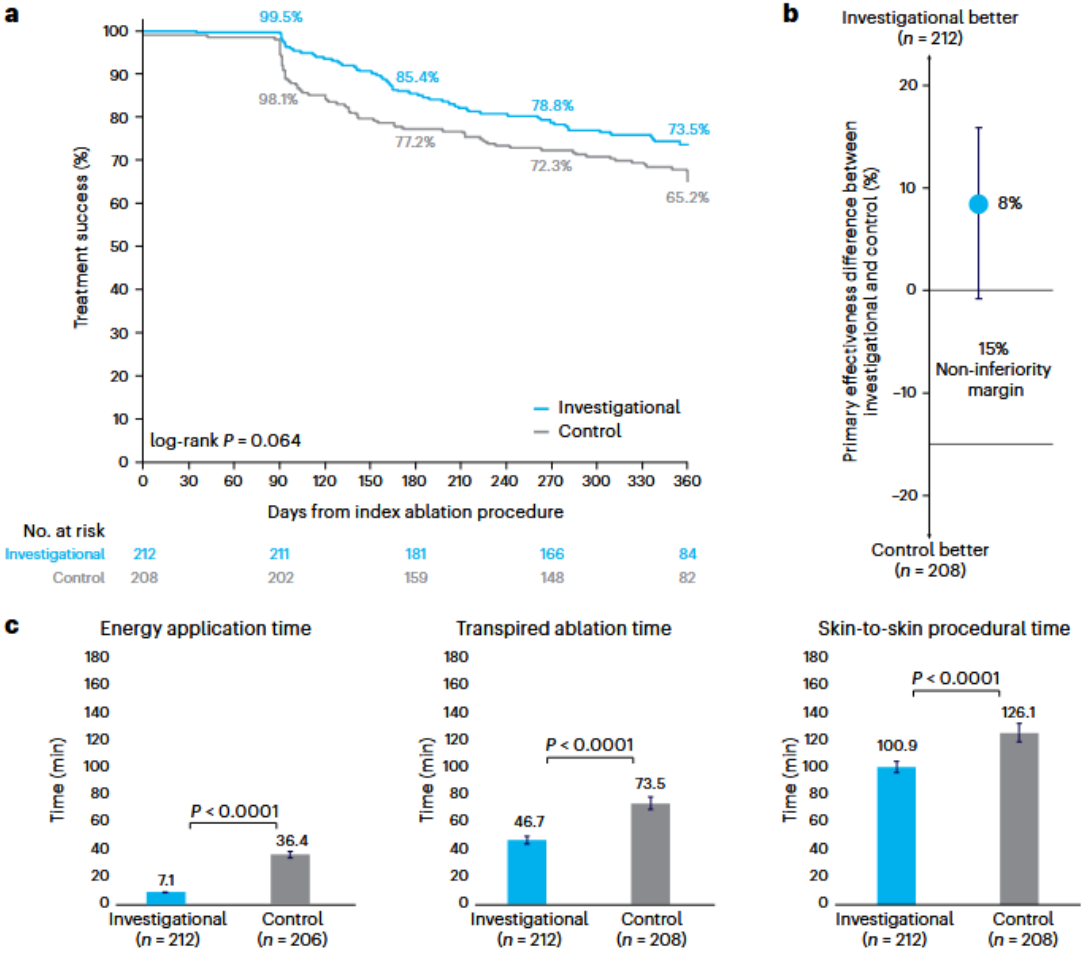
V.Y.Reddy al: JACC EP 2023

Dual-Energy Lattice-Tip Ablation for Persistent AF:

Randomized Trial

423 pts. randomised: **(Exclusion=3)** 420 pts ablation performer: 212 dual-source; 208 standard RF



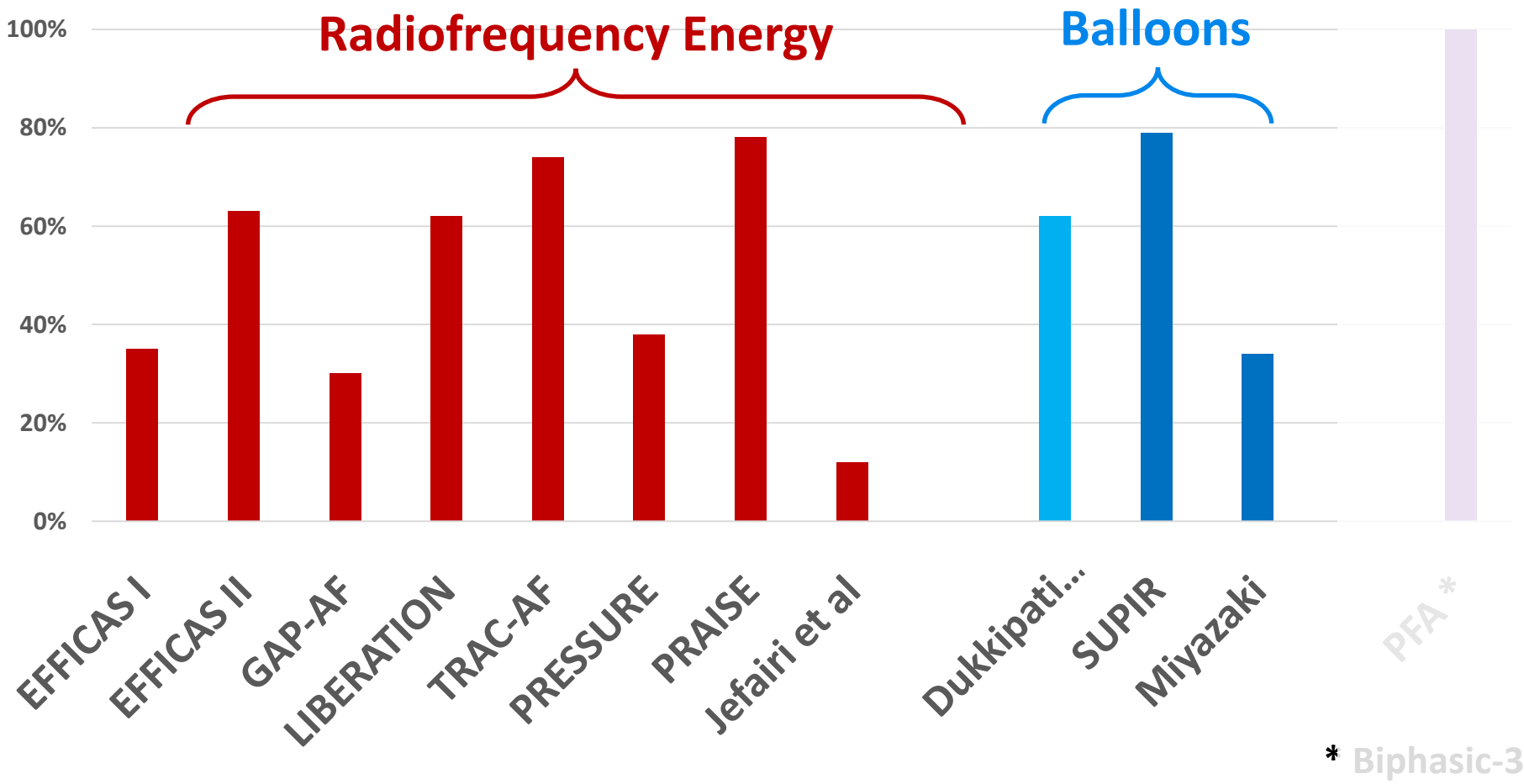


E.Anetr al: Nat Med 2024

Durable PV Isolation

Data from Protocol-Driven Remap Studies

Patients with all PVs Durably Isolated



* Biphasic-3

HOMOLKA Affera Procedures

Data from Registries: Trials & Clinical Practise

First Commercial Pocedure : *January 23, 2024* (Paroxysmal Atrial Fibrillation)

TOTAL Number of Patients: *Clinical Trials: 230 , Clinical Practise: 410* (Total 640 pts)

M / F : 271 / 139, Average Age: 64,5 (21 – 89!), BMI 28,4 (18,3 – 43,3)

Procedures by Indication:

AF -	282	(Paroxysmal 67, Perzistent 199, Long standing Perzistent 16)
AT -	32	(Reentry 16, Focal 18, In combination 3)
VT/VPS -	42	(non structural VOT and others)
Structural VT -	36	(post-MI 23, HCMP 11, Surgery 1, Fascicular)
Other Arrhythmias -		(AVN 1, WPW 1, CNA 32)

Anesthesia :

General Aneshesia -	310
Analgo/sedation -	100

HOMOLKA Affera Procedures

Data from Registries: Trials & Clinical Practise

Re – do Procedures : Total : AF 175 (2nd proc. **70**, 3rd proc. **50**, 4th proc. **30**, 5th proc. **25**)
AT 23

Re – do Procedures AT/AF after PFA (147) :

Farawave -	133
Affera Sphere 9 -	10
Other PF Technology -	4

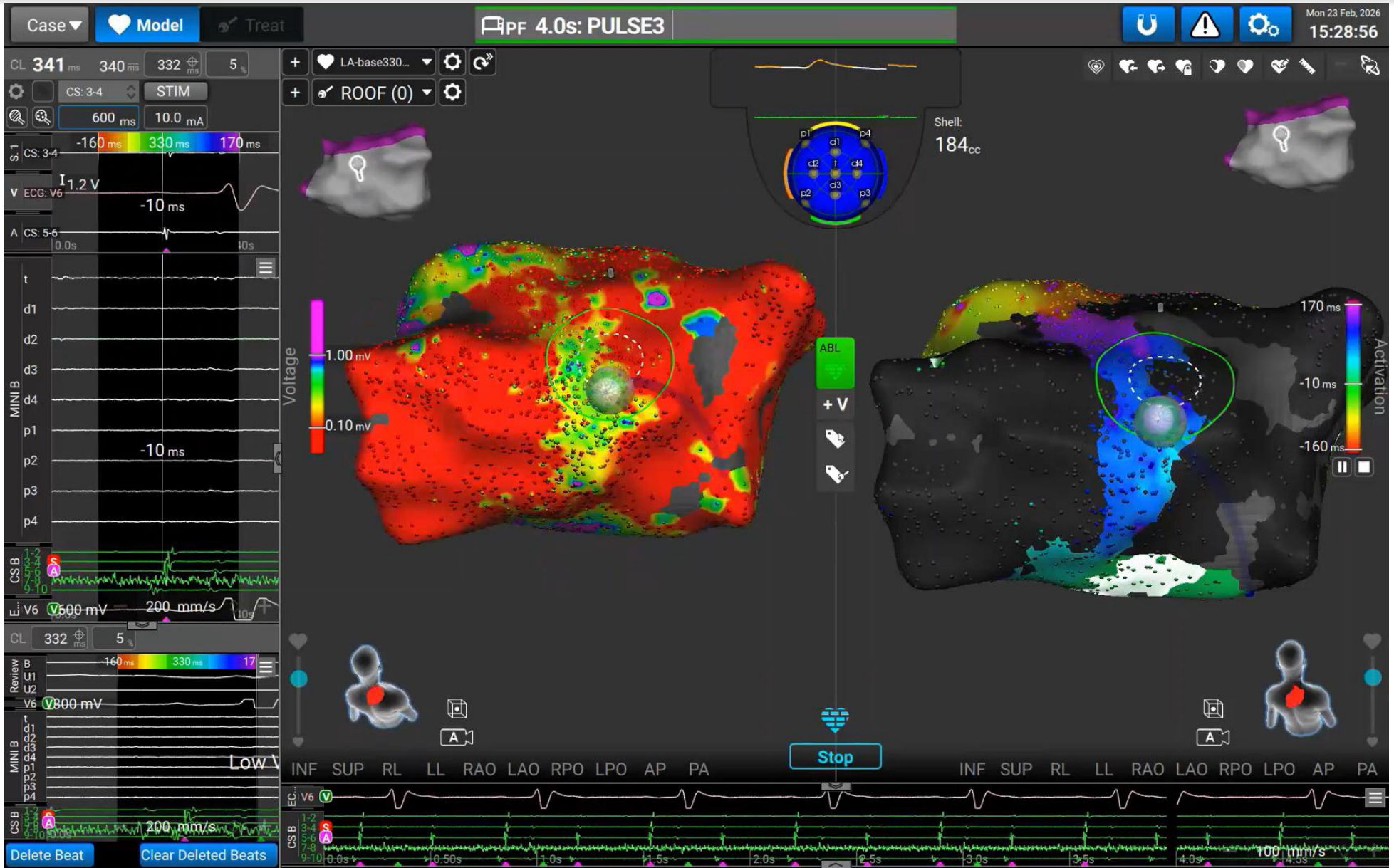
Linear lesions :

Mitral lines -	112
BOX -	107
Anterior lines -	122
CTI -	130
CAFE:	N/A

AFFERA Sphere 360: 68

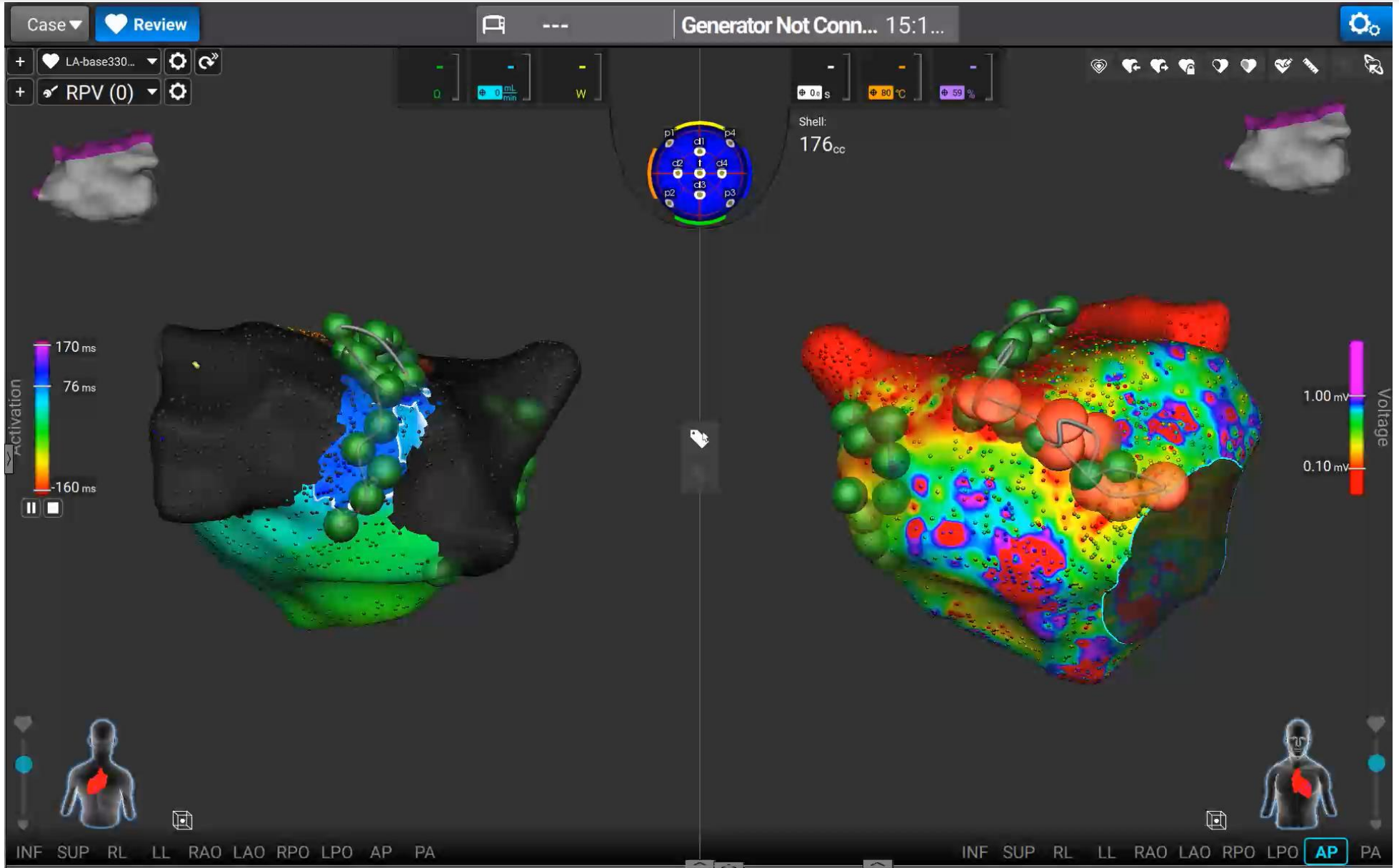
Post PVI & BOX

10 Months after Farawave



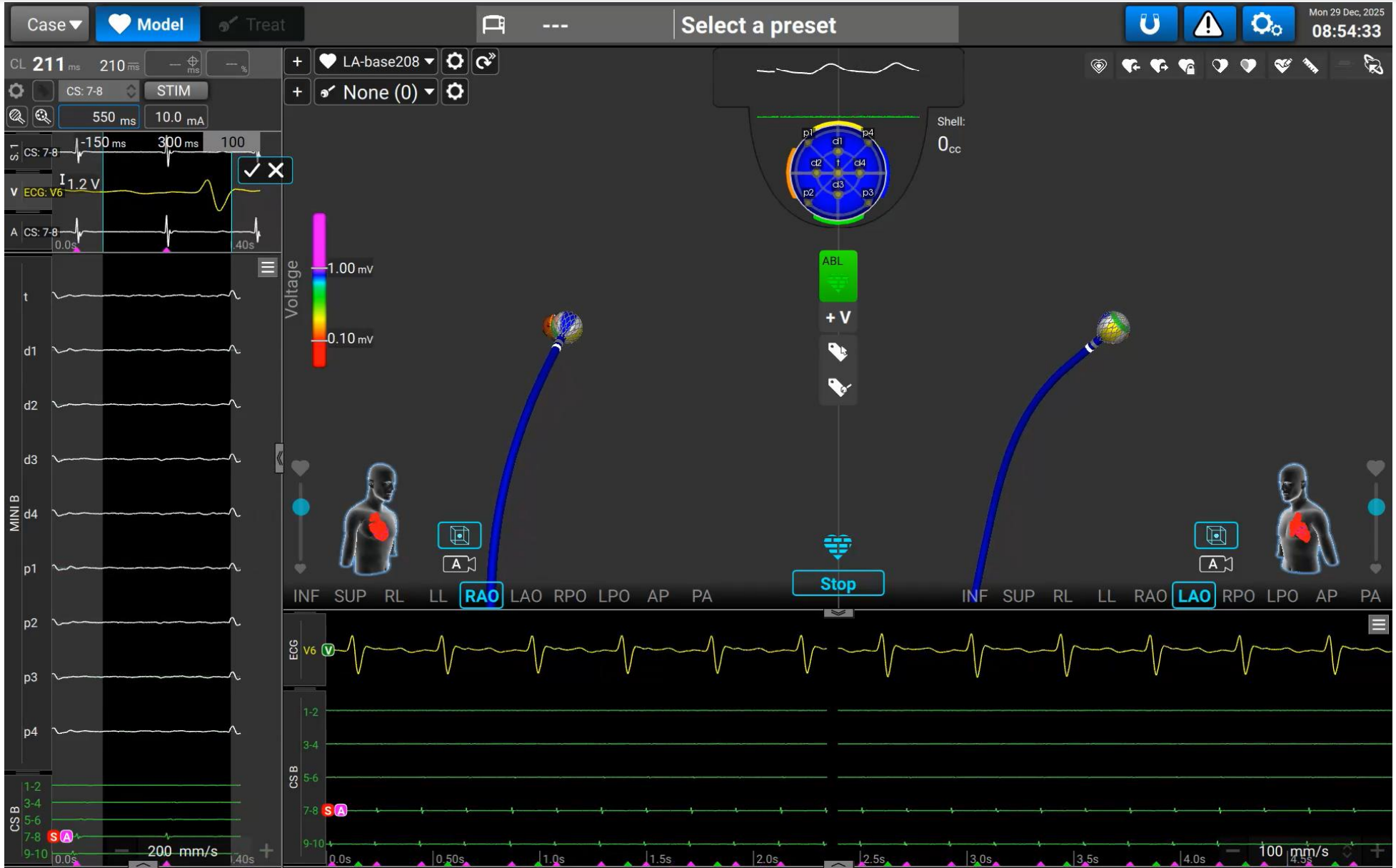
Post PVI & BOX

10 Months after Farawave



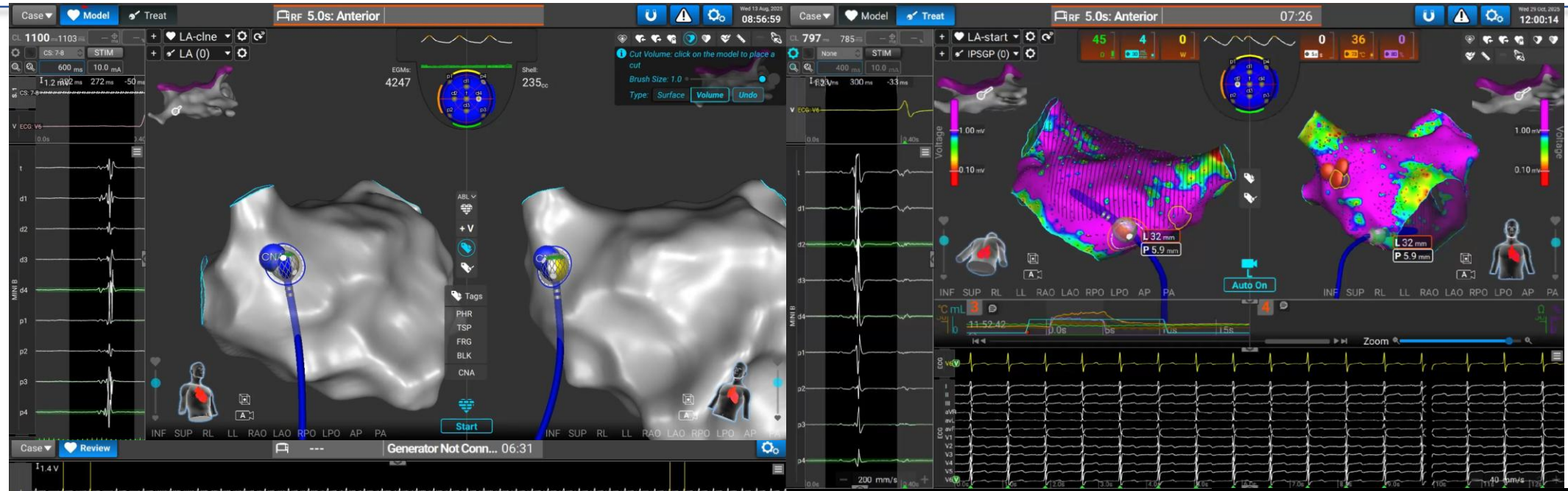
Post PVI & BOX

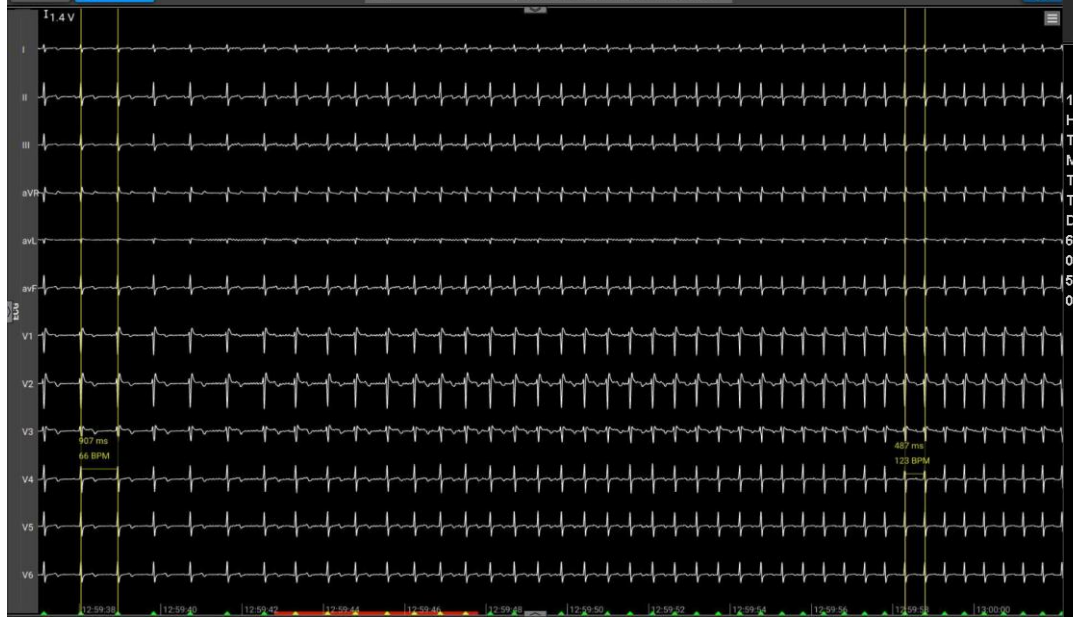
22 Months after Farawave

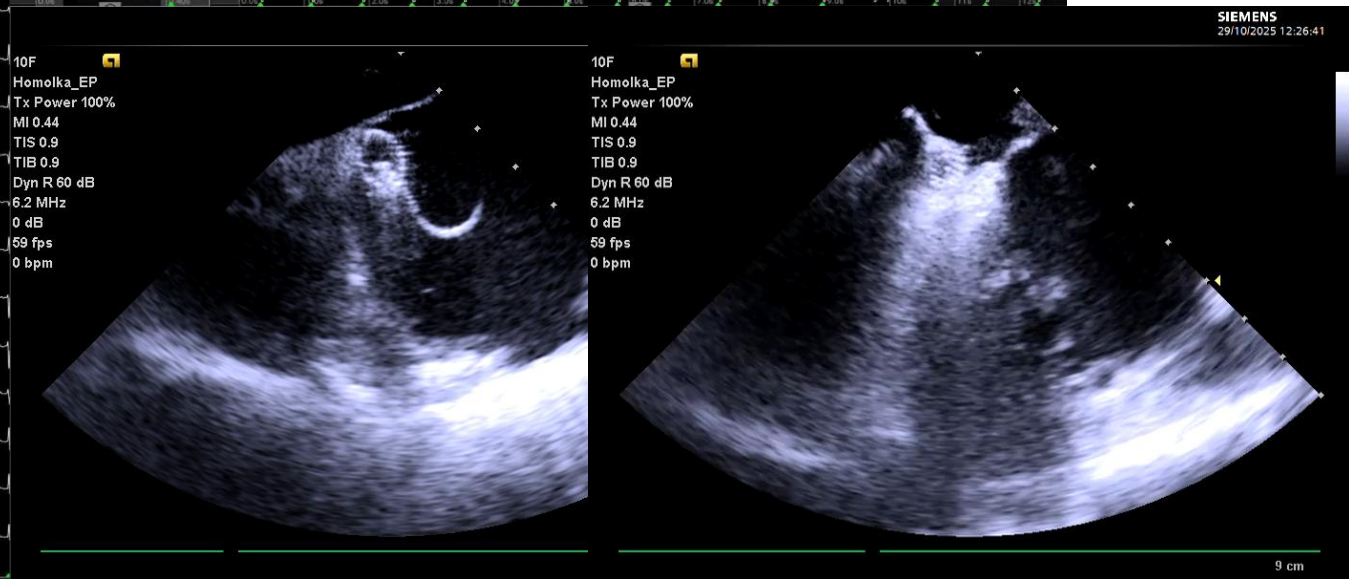


Cardio Neuro Ablation

Sub PA Valve RF only

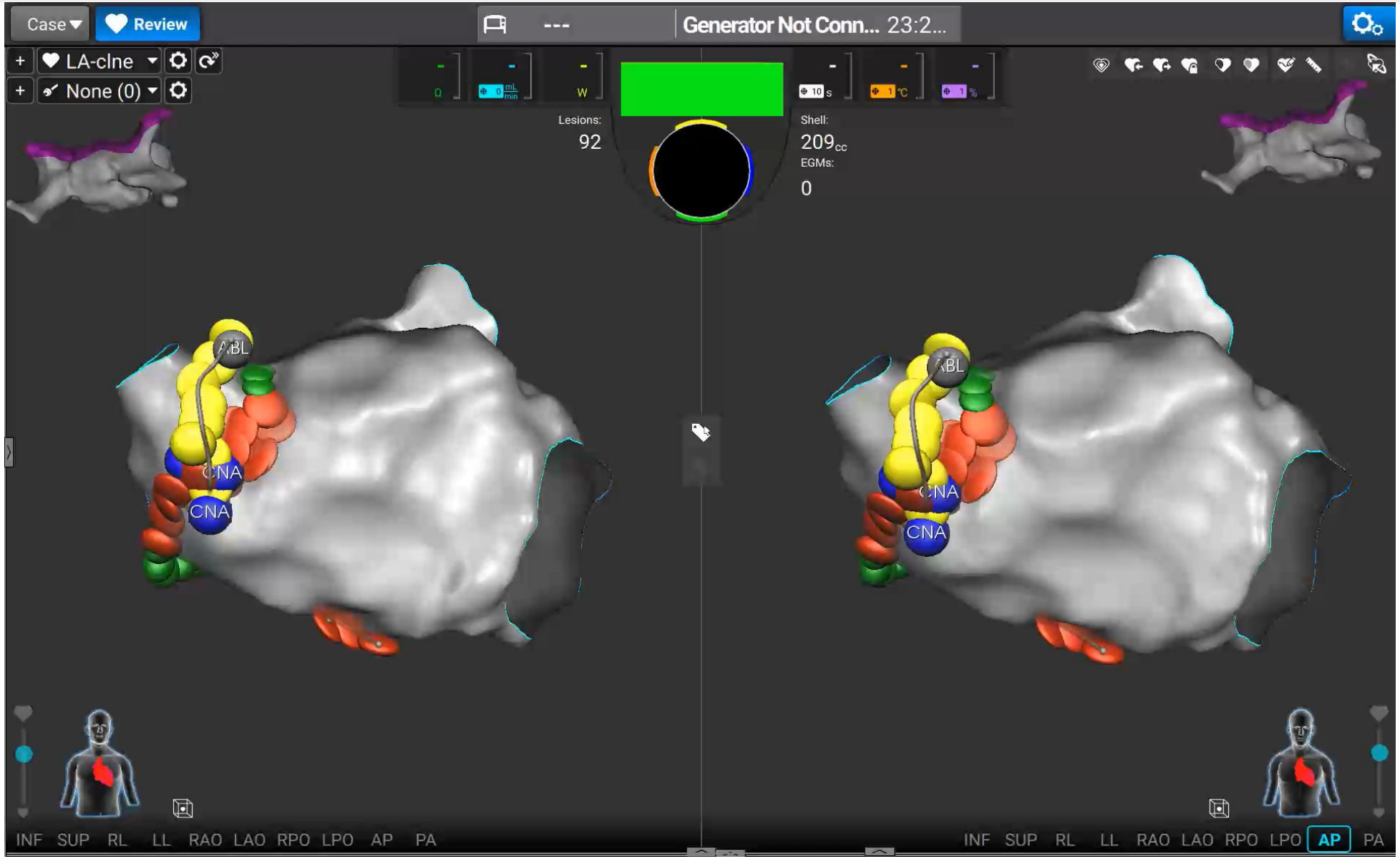






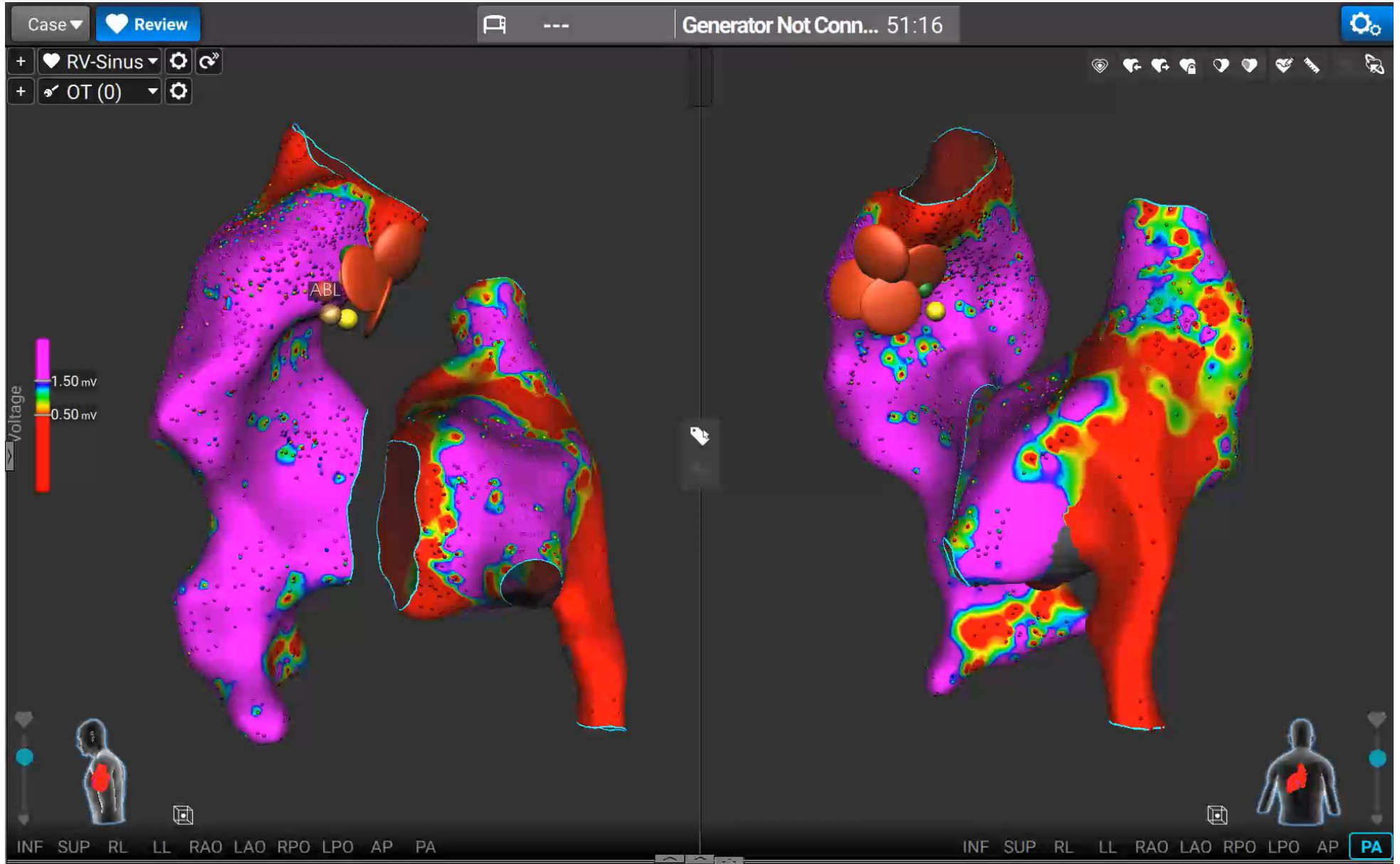
Cardio Neuro Ablation

Sub PA Valve RF only



RVOT VT

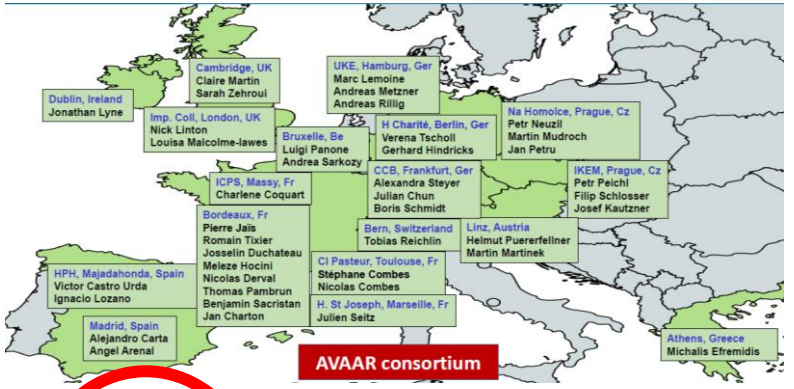
Sub PA Valve RF only



AVAAR Registry

Lattice-Tip Structural VT Ablation

- European Registry, 16 centers, 126 pts.: 99x VT, 4x VF, 23x PVC



Conclusions

- **Extremely sick population with complex VA**
  - 2/3 of them referred for redo procedure
- **Limited data on optimal energy delivery strategy**
  - Recurrence in patients with 4 PFA applications, mixed of RF + PFA?
- **Safety**
  - Based on the population included, same range as published data
  - No hemolysis with clinical consequence identified in this registry so far
  - Stroke: need to be carefully monitored
- **Efficacy**
  - 68% absence of recurrence at 6 months for patients with redo procedure

➢ **Efficacy**

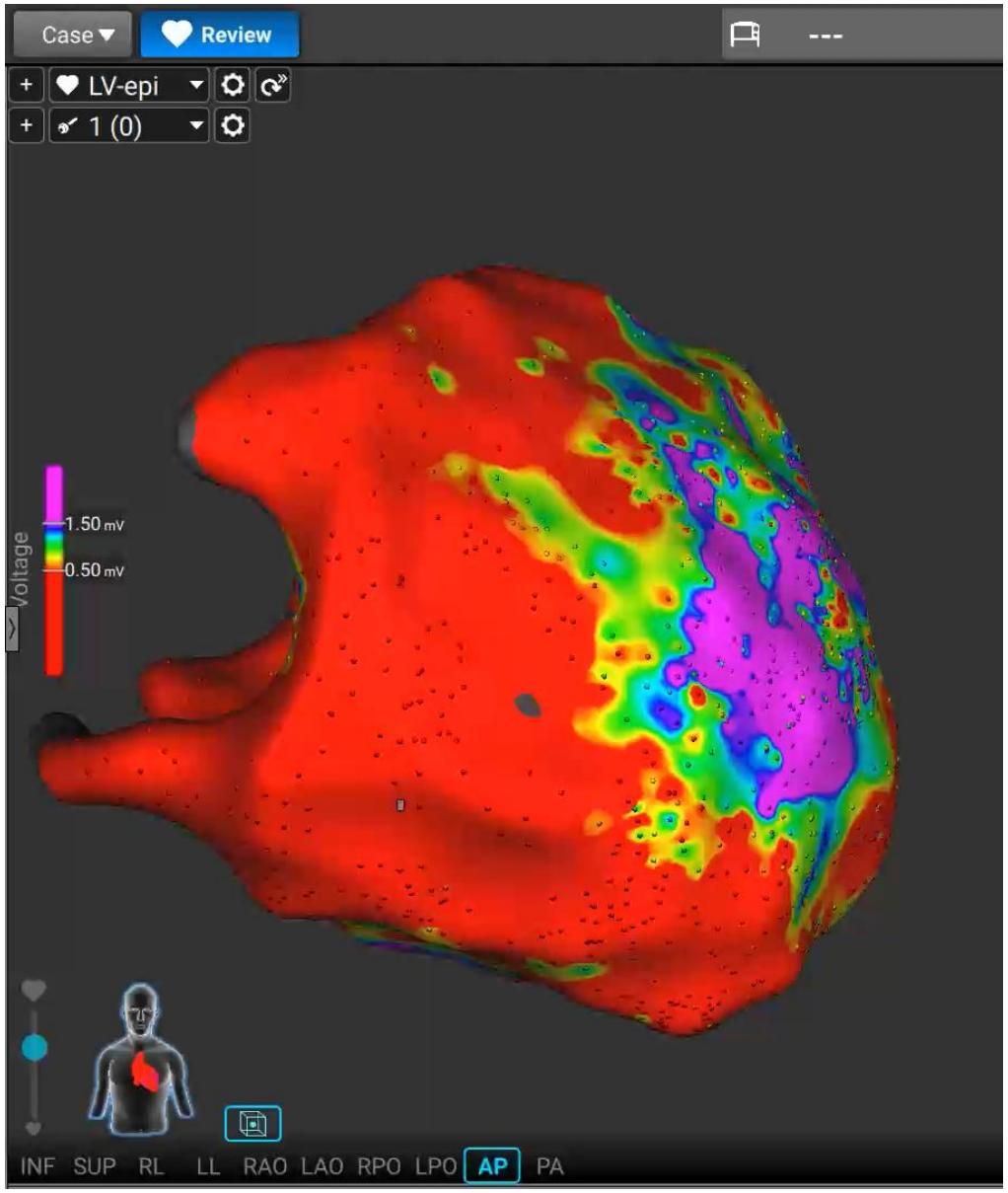
	VT (n=99)	VF (n=4)	PVC (n=23)
Absence of recurrence	69/99 (70%)	4/4 (100%)	18/23 (78%)
Follow-up (month)	6 ±4	6 ±4	4 ±3

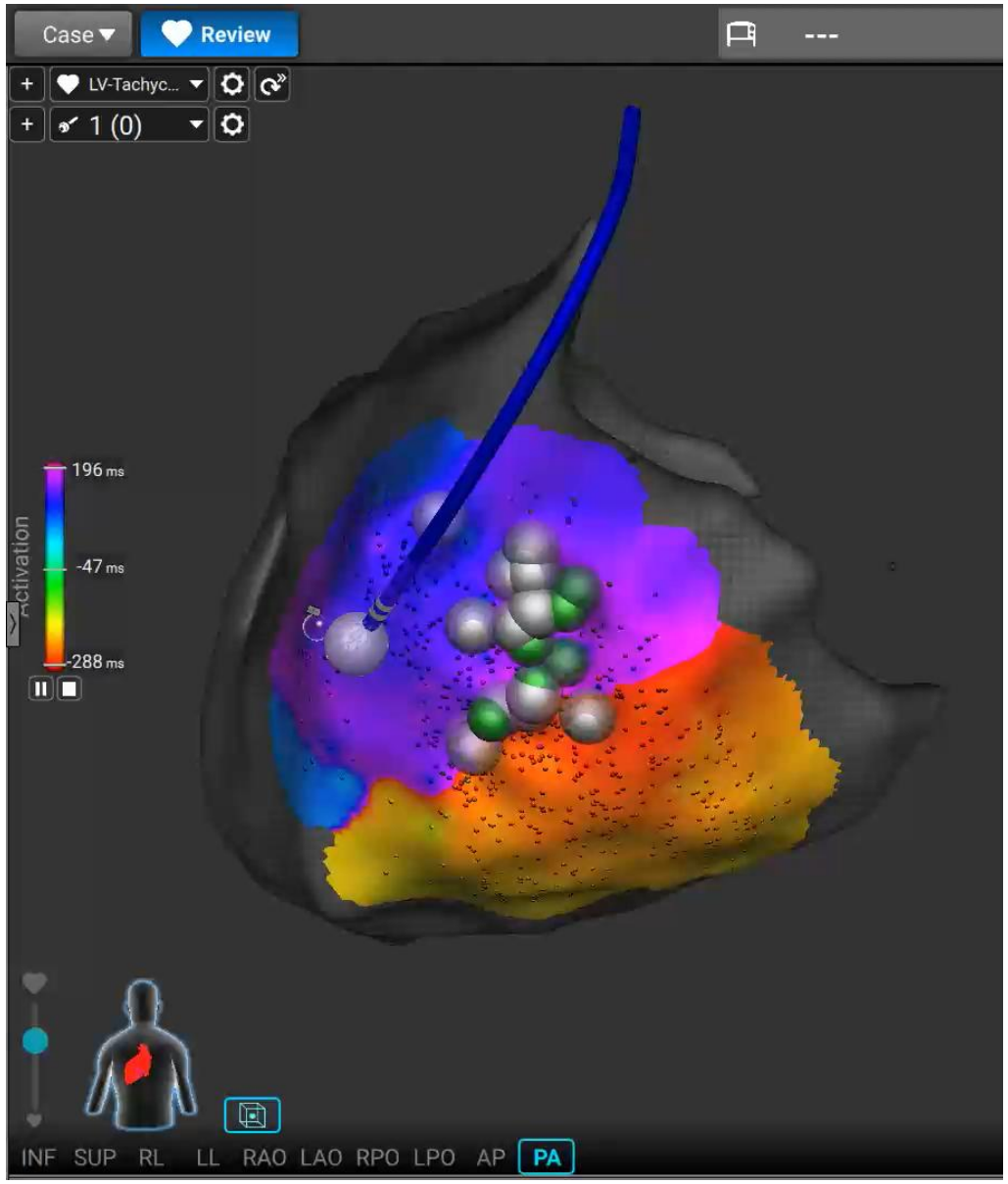
Mortality: 3% of all pts/survey

F. Sacheret al: Europace 2025

Post IM VT

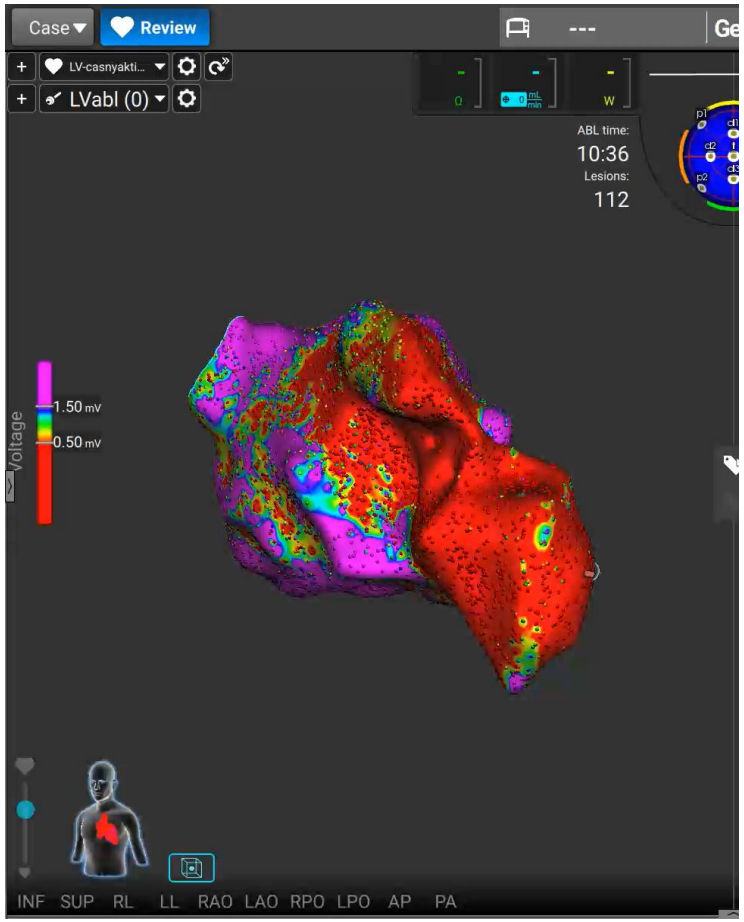
Endo/Epi Mapping of Post Ablation LV

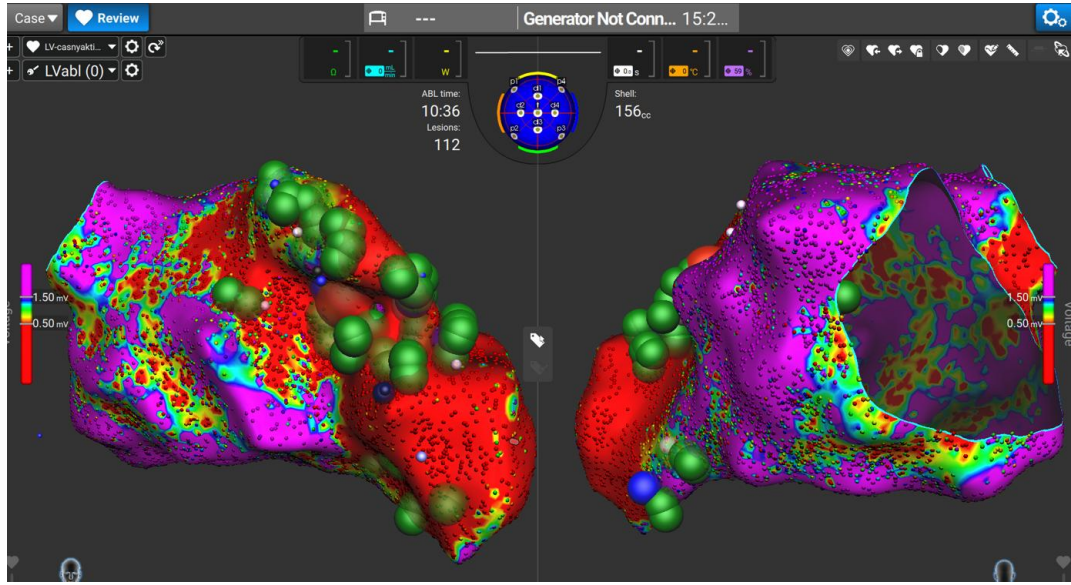




Post IM VT

Revivent Hybrid LV Aneurysmectomy

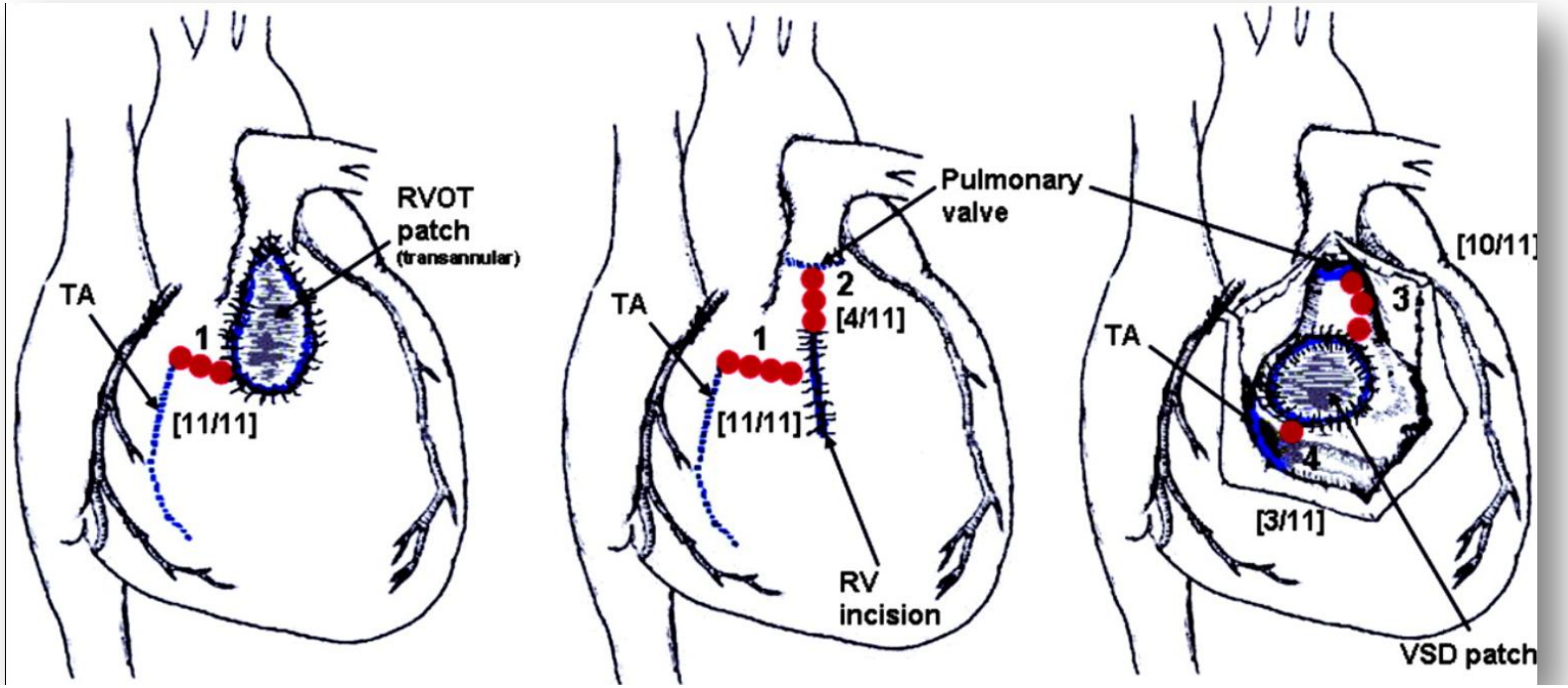


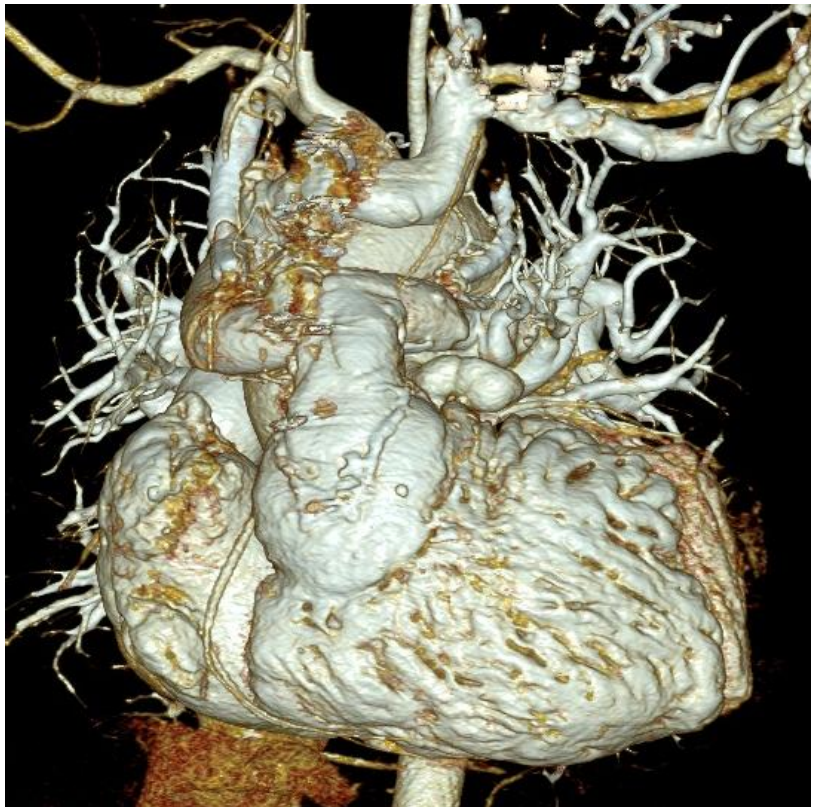


Cogenital Heart Diseases

Atresia of PA with Ventricle Septal Derfect

- 44 yow, after heart surgery (3x) radical correction with VSD closure (dacron) PA stem reconstruction (epicardial aortic homograft)
- Recurrent VTs & ICD shocks



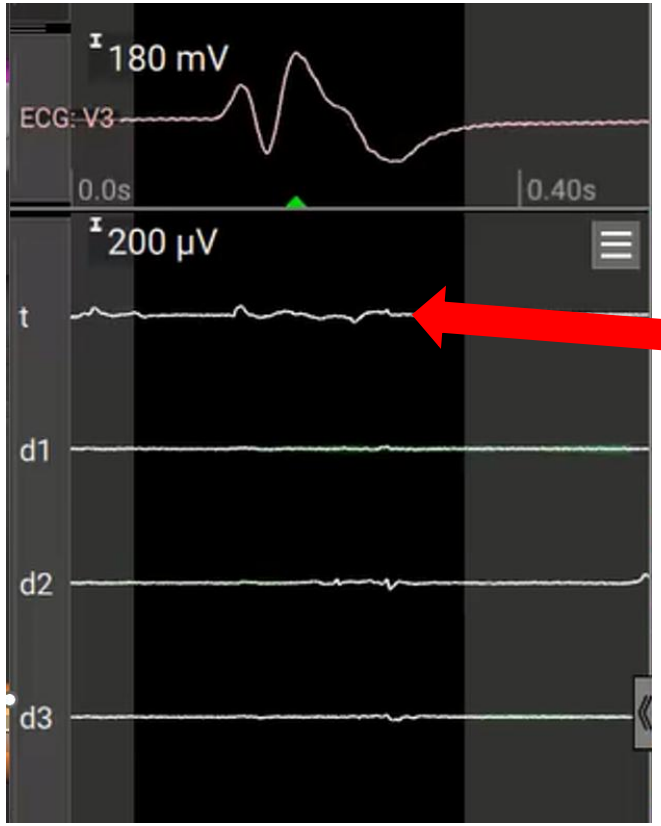


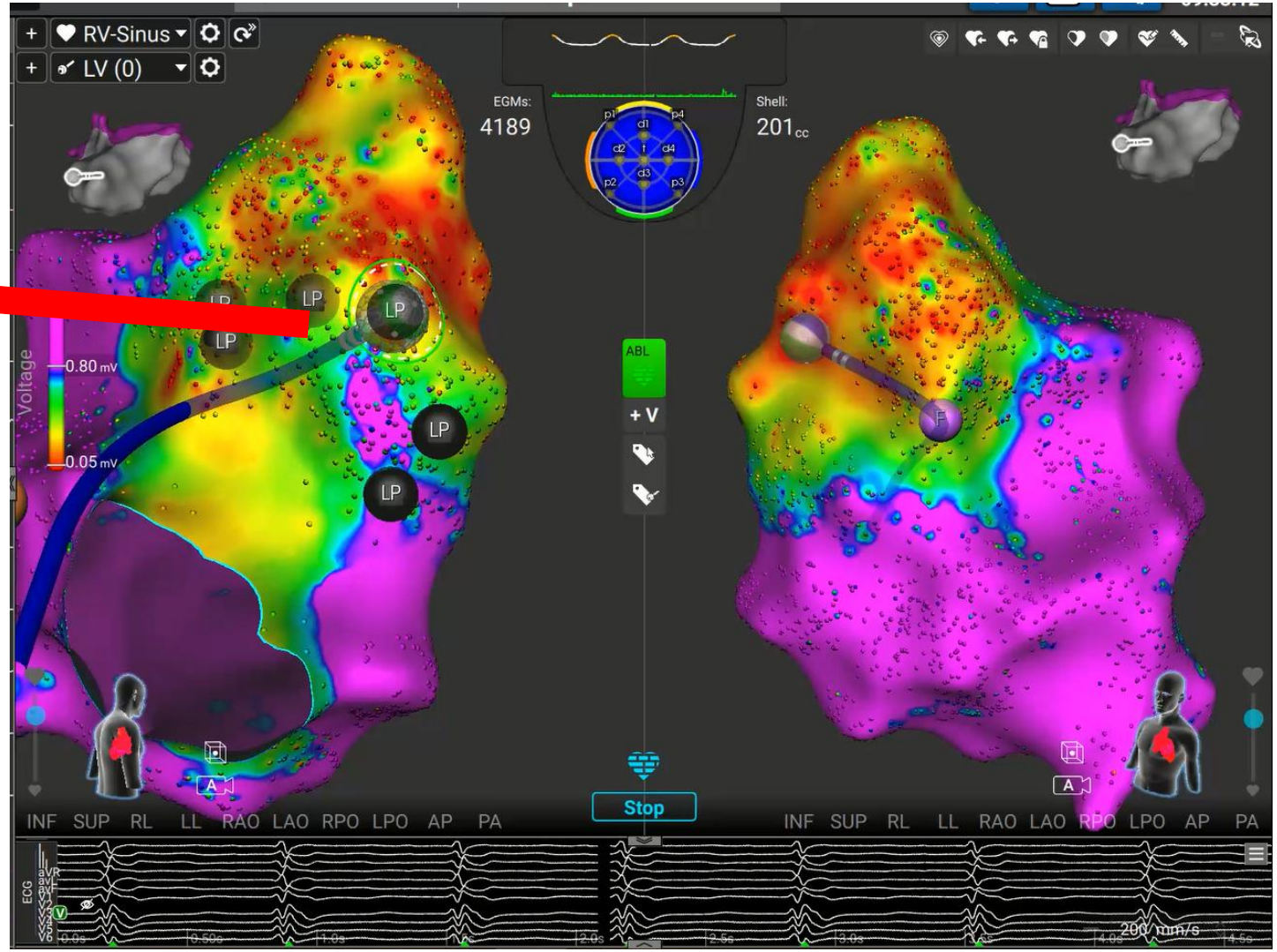
K. Zeppenfeld, Circulation, 2007

Cogenital Heart Diseases

Atresia of PA with Ventricle Septal Derfect

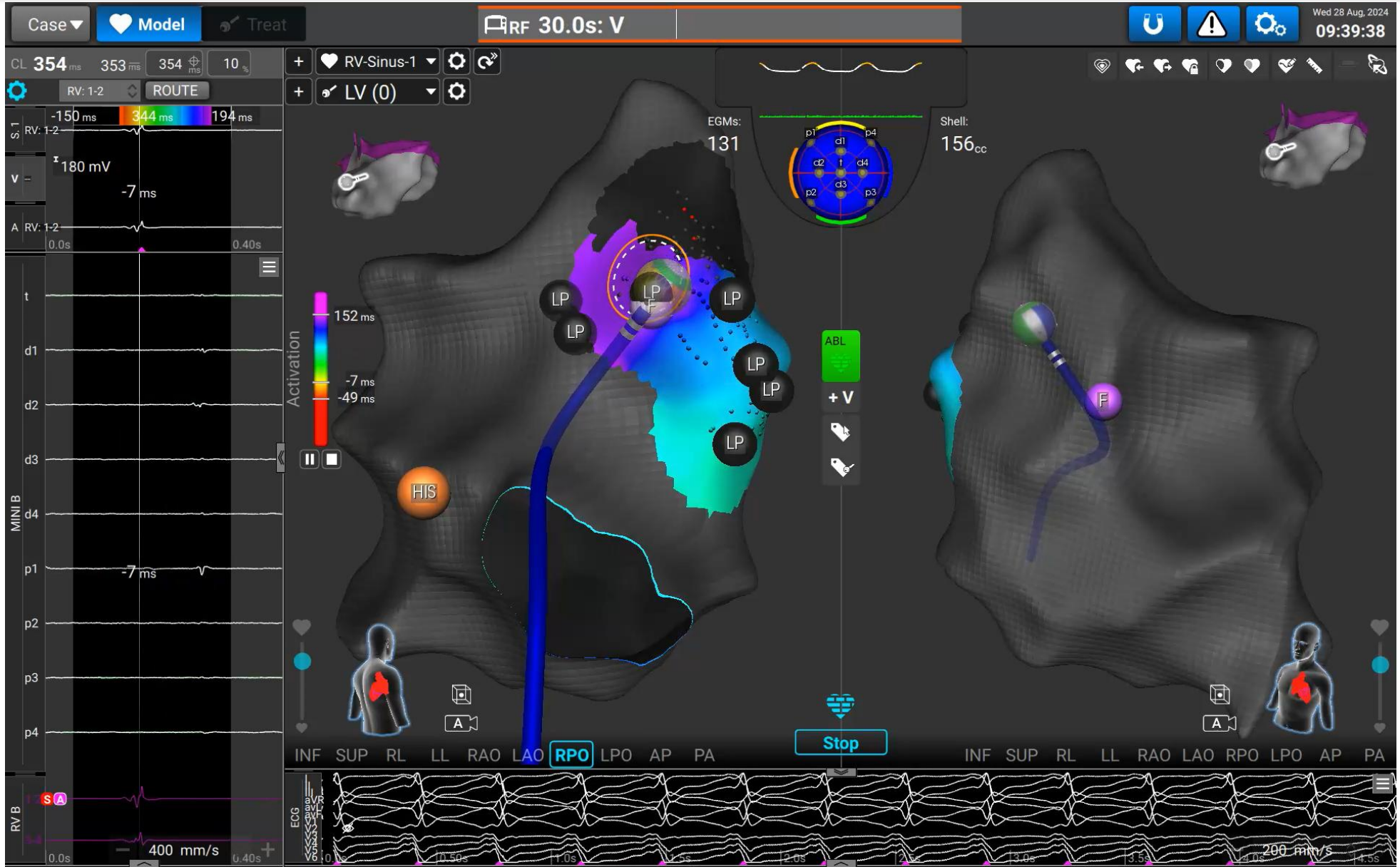
Right Ventricle Substrate Map with Copntinuous Local Potential





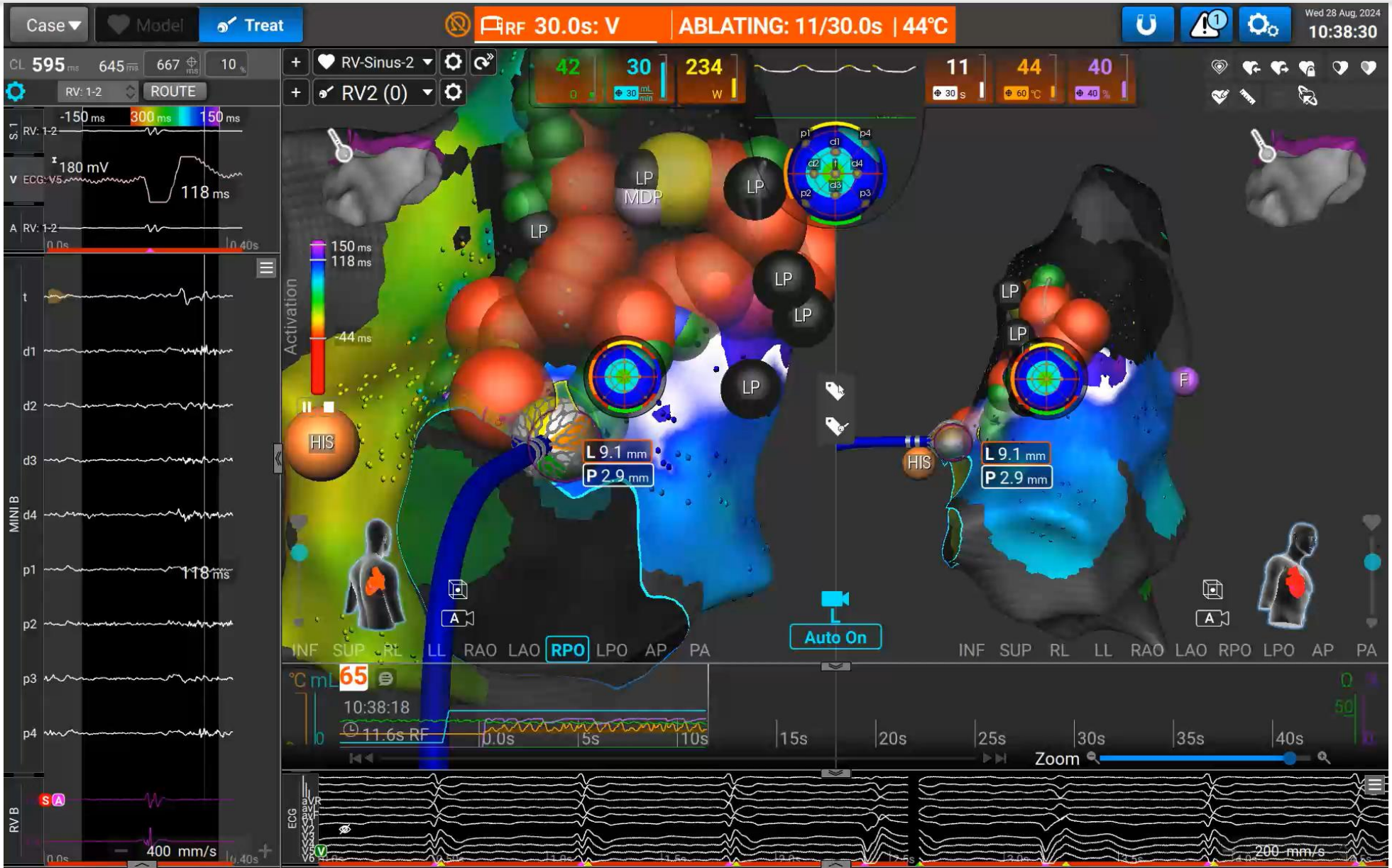
Cogenital Heart Diseases

Atresia of PA with Ventricle Septal Derfect



Cogenital Heart Diseases

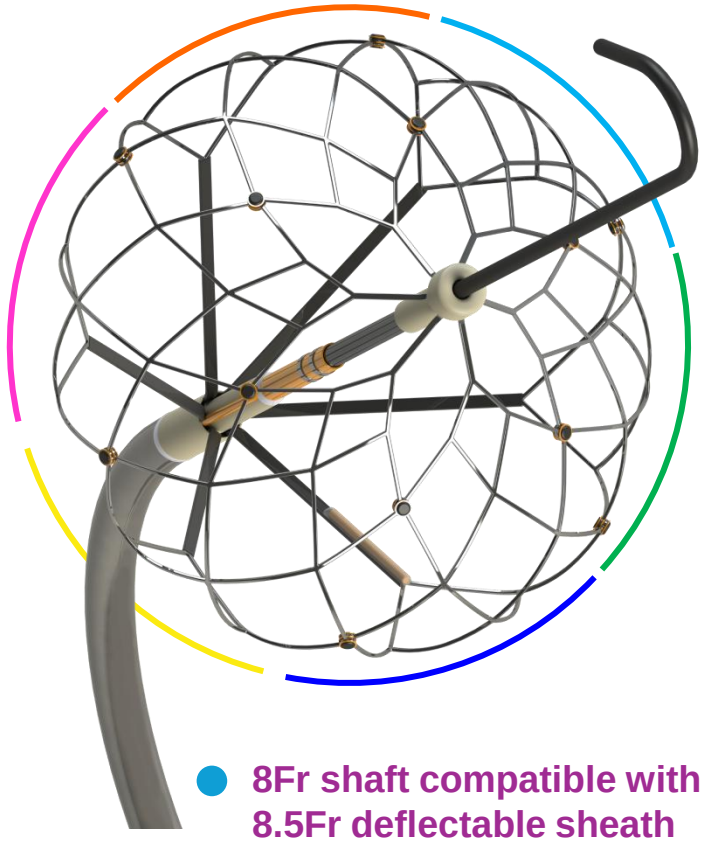
Atresia of PA with Ventricle Septal Derfect



Conformable PFA Catheter: Sphere 360°

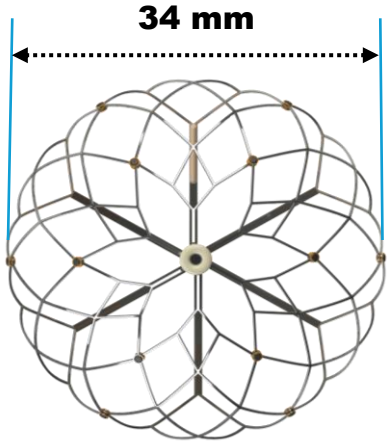
The „First in Man“ Series

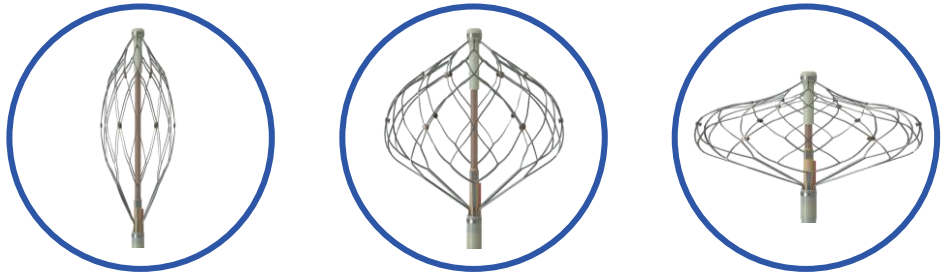
- **Rotation Free Ablation**
  - 4 applications per PV
- **Tissue Conformable Lattice Tip**
  - Energy delivered thru the entire lattice
- **All-in-One Mapping and Ablation**
  - **6 bipolar electrode pairs** provide pacing, EGM sensing, mapping and stimulation
  - **Local impedance measurement** for catheter and tissue proximity
  - **Single transeptal** puncture
- **Electromagnetic Sensors**
  - Allow tracking, shape visualization, catheter orientation, tagging, & EAM/activation/voltage mapping



- **8Fr shaft compatible with 8.5Fr deflectable sheath**
  - Over-the-wire design

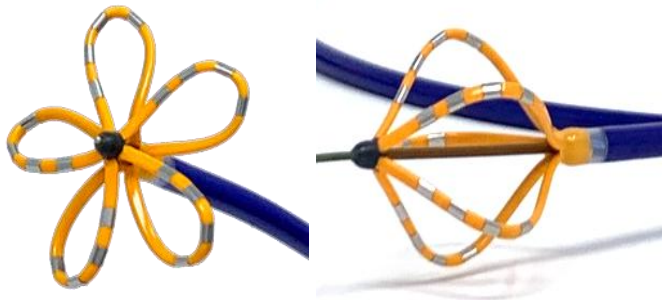
- **6 Sections**
  - Independently and sequentially energized
- **Shape Adapting Design**
  - Expandable to 34 mm
  - Adaptable to varying PV anatomies
- **Unipolar Biphasic Waveform**
  - 5.9 sec per application





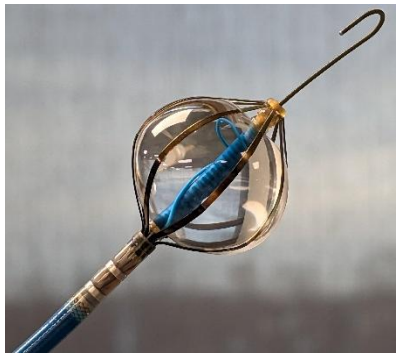
Pulsed Field Ablation

Catheter Technology for AF (In Clinical Trials)



CE: First PFA approved

FDA in US

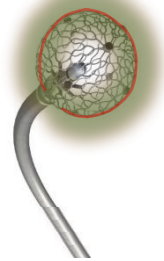


CE in (EU)

CE in (EU)

Focal PFA

Lattice-Tip: RF/PF

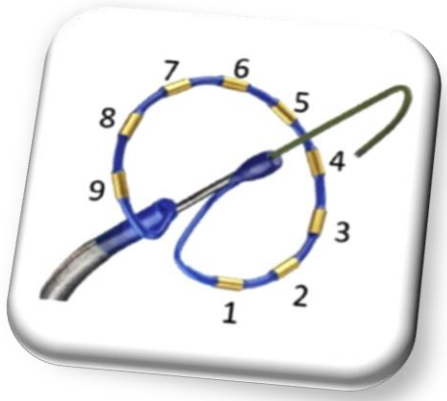


Gold-Tip: RF/PF

(CE EU)

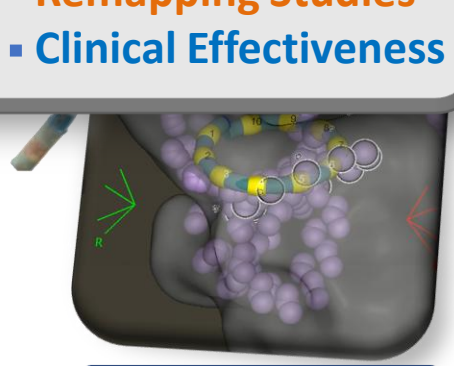
Remapping Studies

Clinical Effectiveness



Fist PFA FDA in US, CE in EU

CE study in (EU)

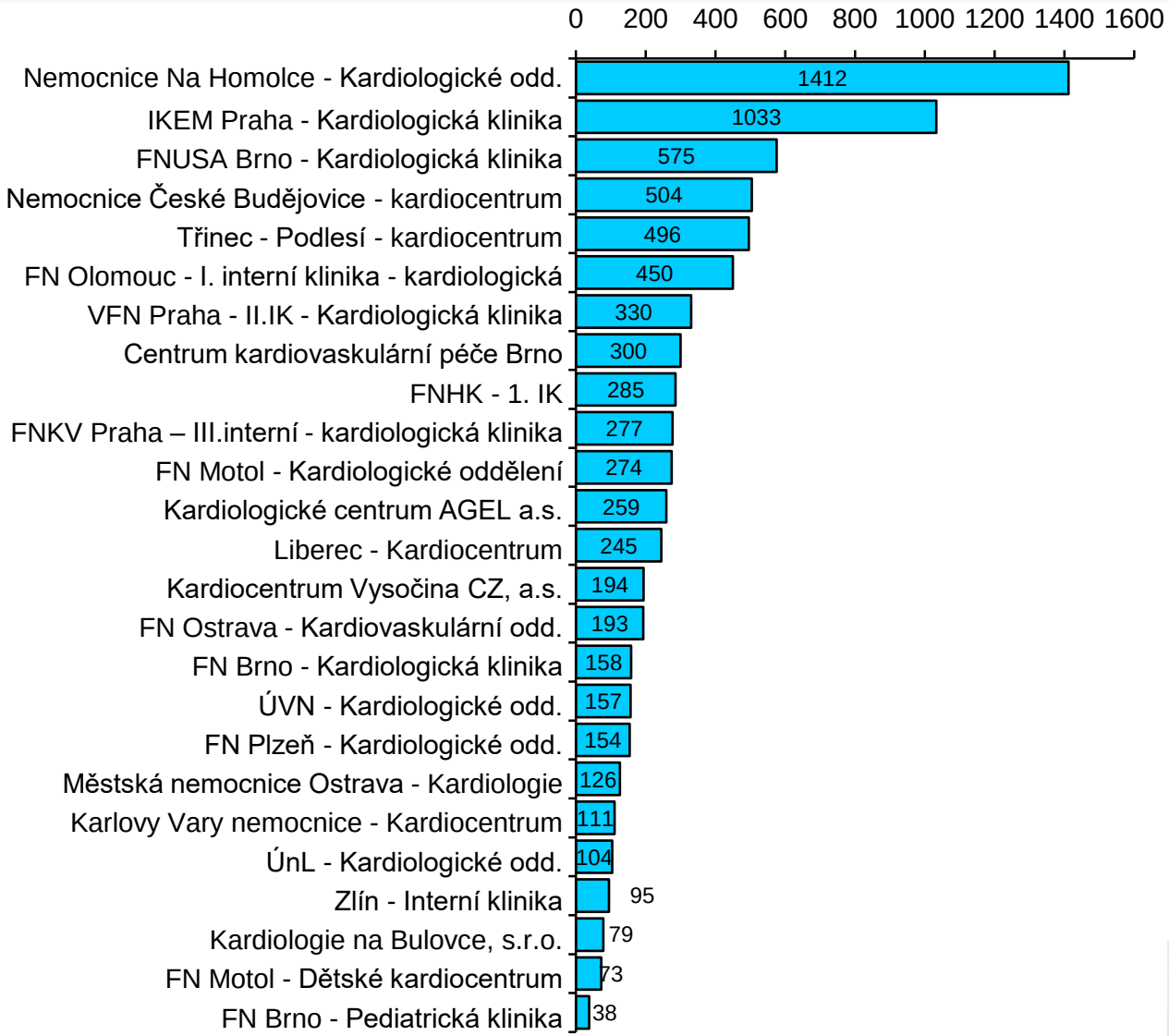


FDA in US, CE in EU

FDA in US not CE in EU

FIH trial Ongoing (EU)

Register of Catheter Ablation ČASR 2019



Number of procedures

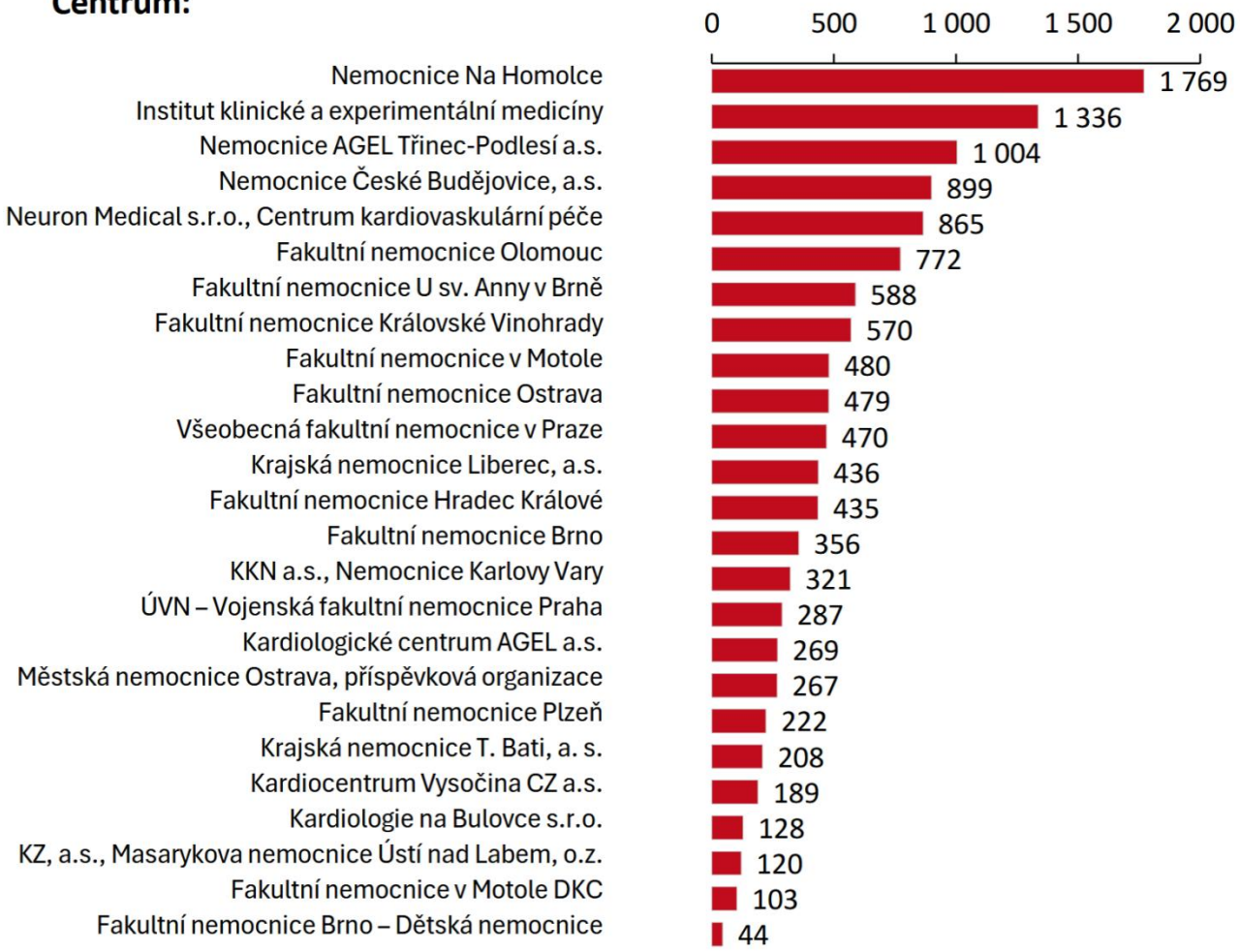
(N = 7 918)

XXXIV. VÝROČNÍ SJEZD ČESKÉ KARDIOLOGICKÉ SPOLEČNOSTI

Register of Catheter Ablation ČASR 2024

Počet provedených výkonů v roce 2024 (N = 12 617)

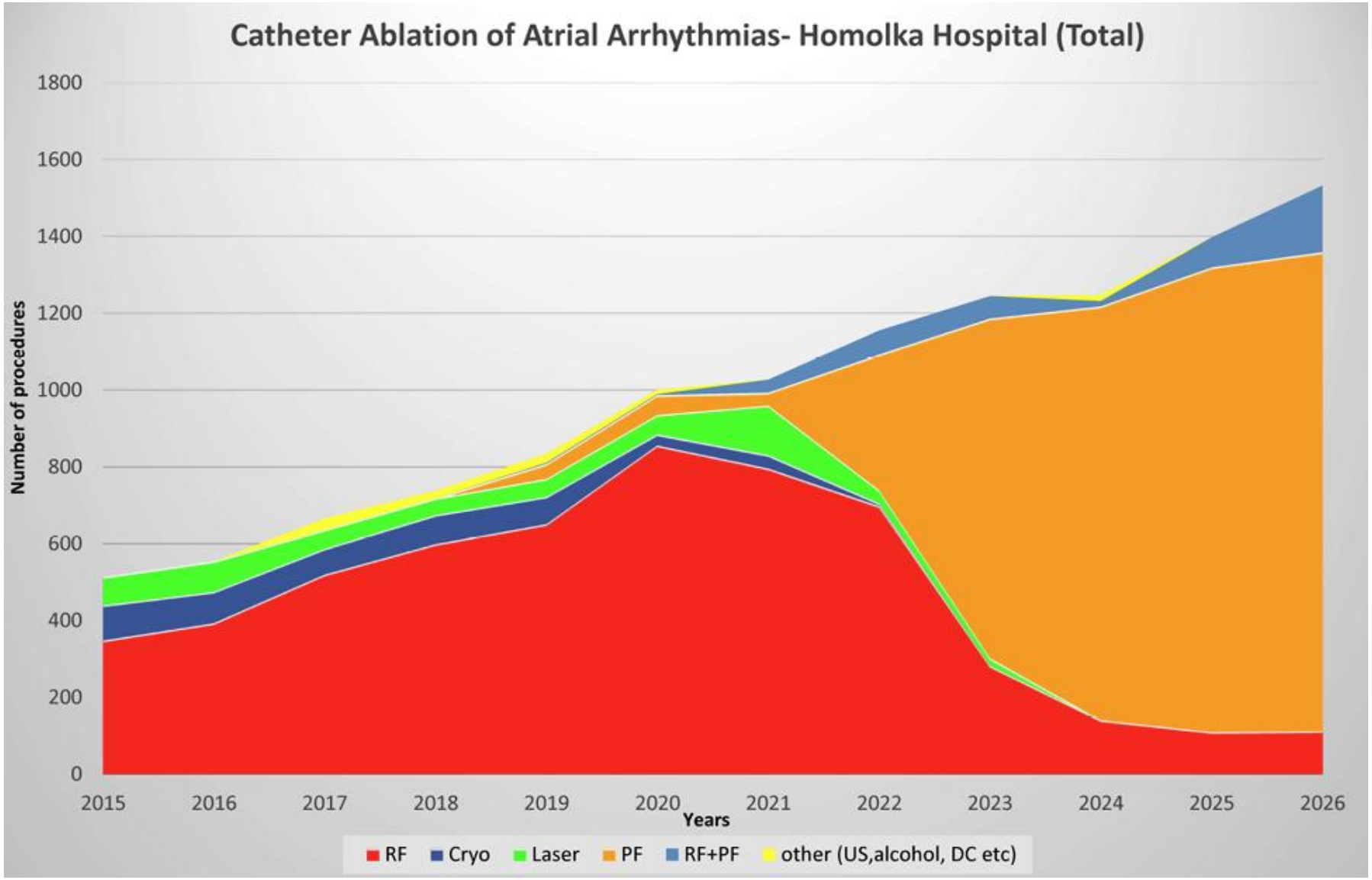
Počet provedených ablací v roce 2024



FUTURE OF TECHNOLOGIES ?

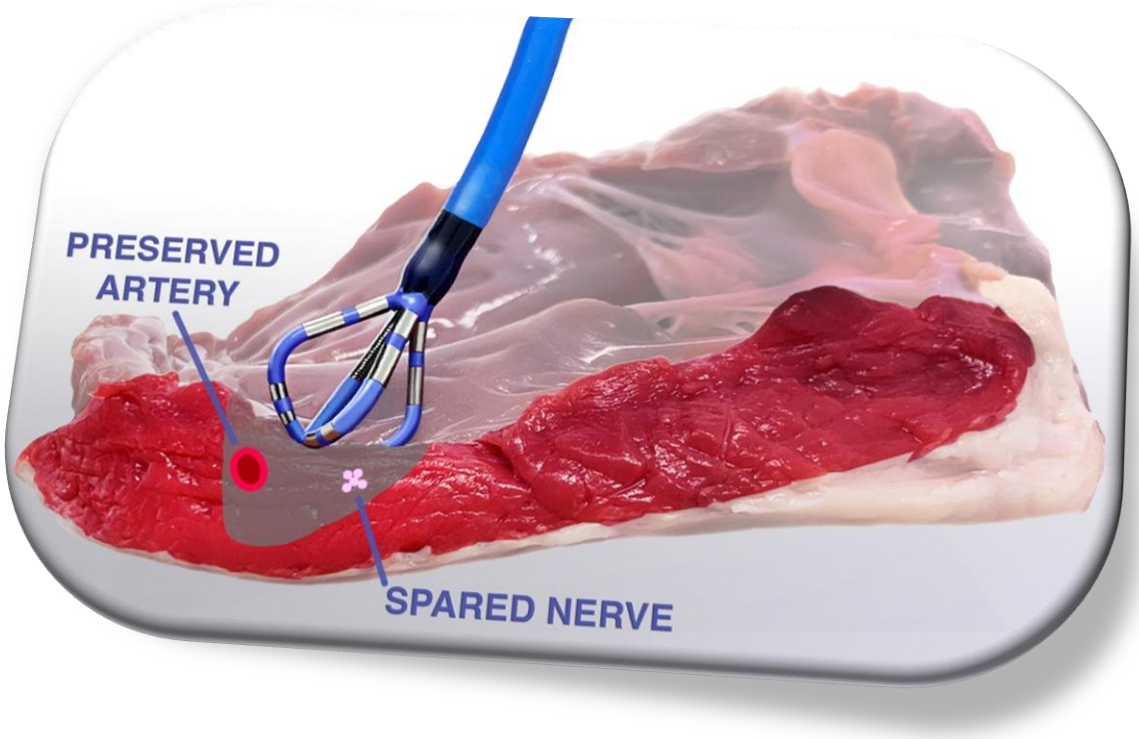
New Technology Adoption

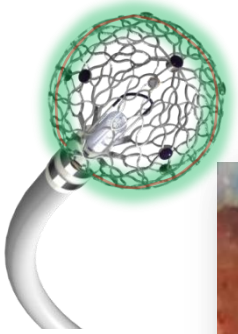
AFib Catheter Ablation in Homolka Hospital – Includin Clinical Trials

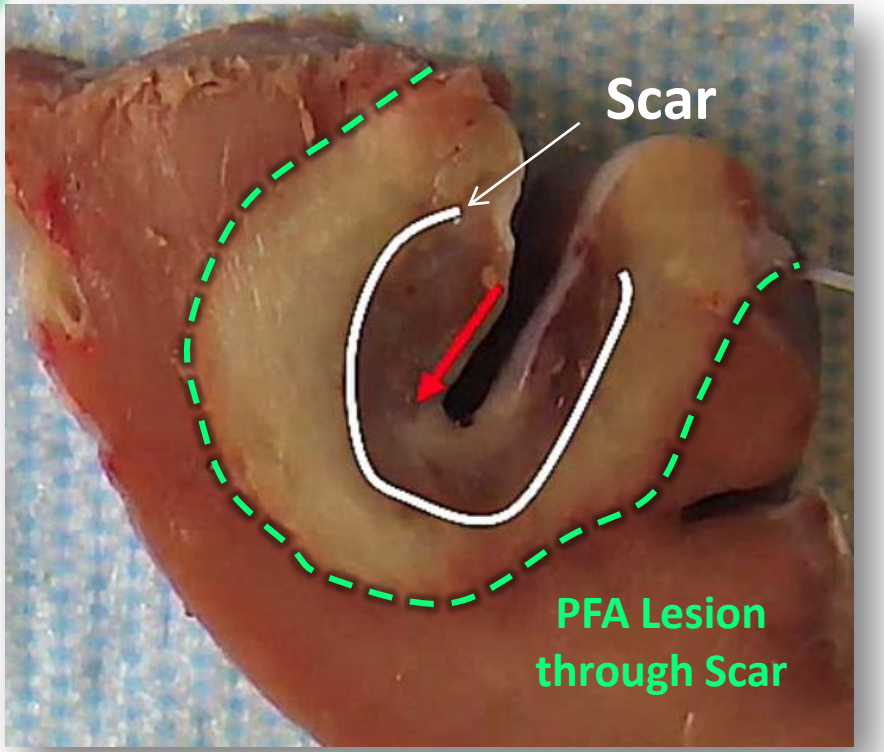


Importance of Preclinical Testing

High Voltage Puls
PFA - Electroporation!!!!







Koruth JS, Kuroki K, Iwasawa J, … Reddy VY. *Europace* 22, 434–439 (2020)
JS.Koruth / E. Anter / VY.Reddy (*HRS – 2021*)