



# ELECTRA

5-6 DÉCEMBRE 2024

HOTEL VILLA MASSALIA,  
MARSEILLE | FRANCE

18<sup>èmes</sup> journées françaises  
pratiques de rythmologie  
& de stimulation cardiaque

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2004 - 2024

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ELECTRA

## FA Persistante: L'électroporation

Dr jp Albenque

- Consultant: Medtronic, Abbott, Volta

# PFA for atrial fibrillation ablation

- Various technologies and catheter designs from different companies

- Farawave (Farapulse, BSCi)



- Varipulse (Biosense Webster)



- PulseSelect (Medtronic)



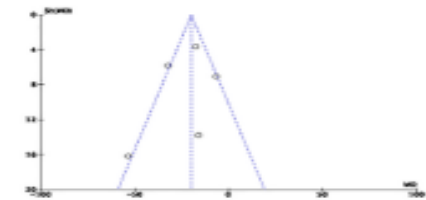
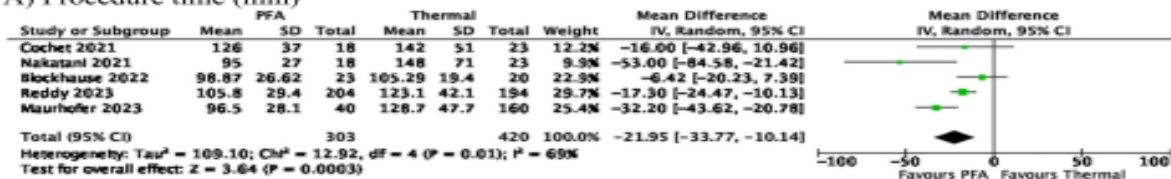
- Sphere-9 (Affera, Medtronic)



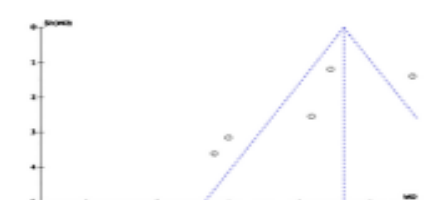
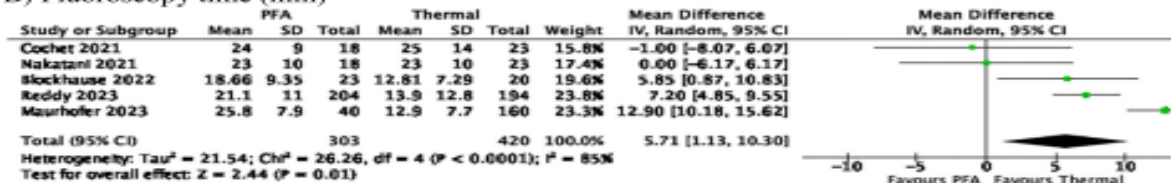
- More to come ...

# Pulsed field ablation versus thermal energy ablation for atrial fibrillation: a systematic review and meta-analysis of procedural efficiency, safety, and efficacy

## A) Procedure time (min)



## B) Fluoroscopy time (min)



## C) Periprocedural Complications

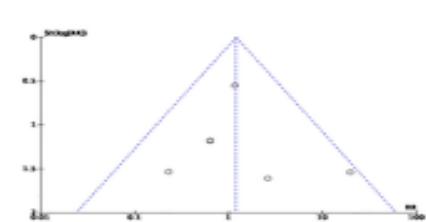
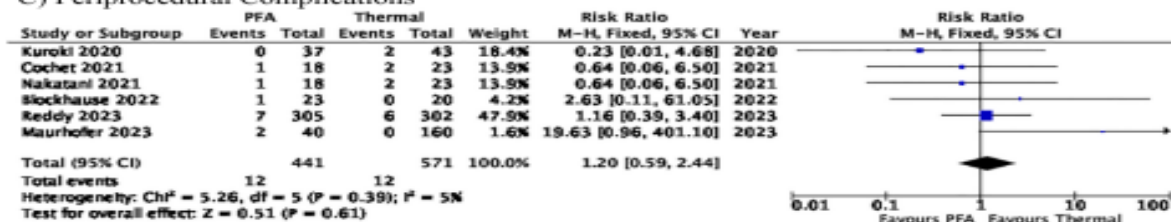
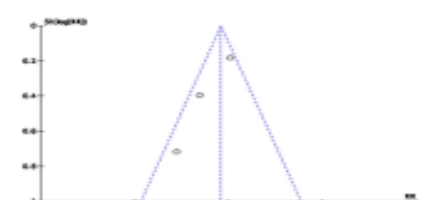
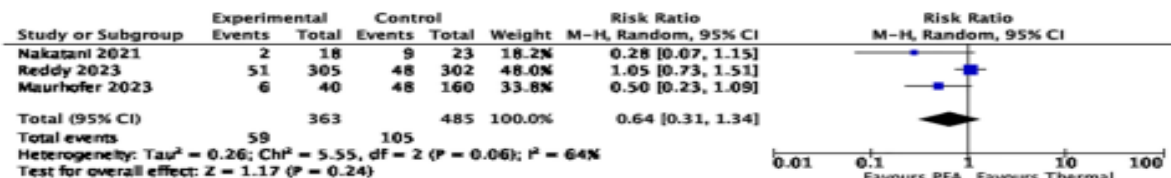


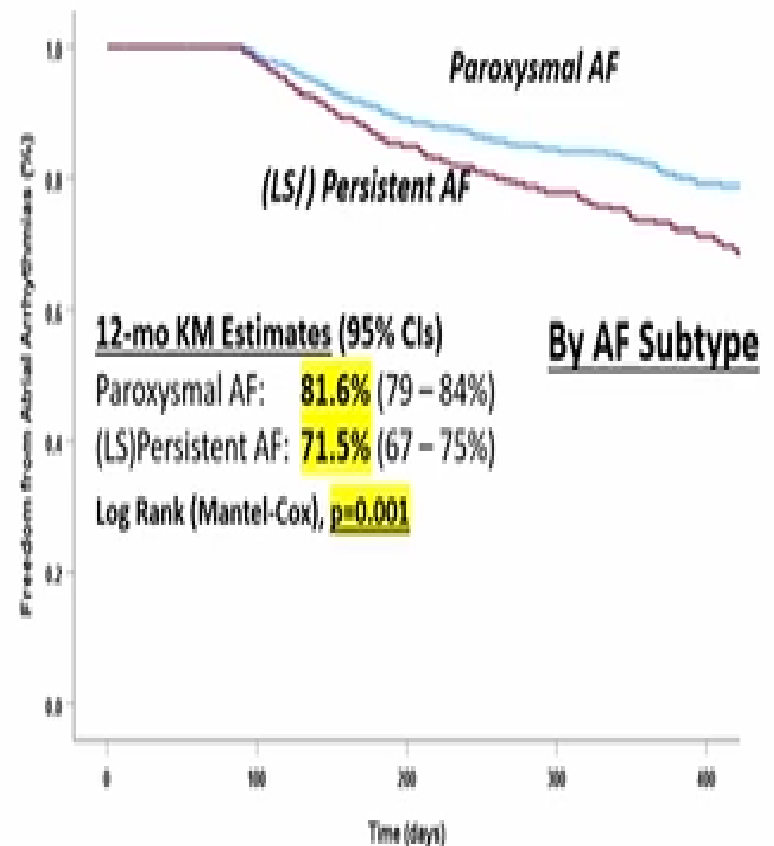
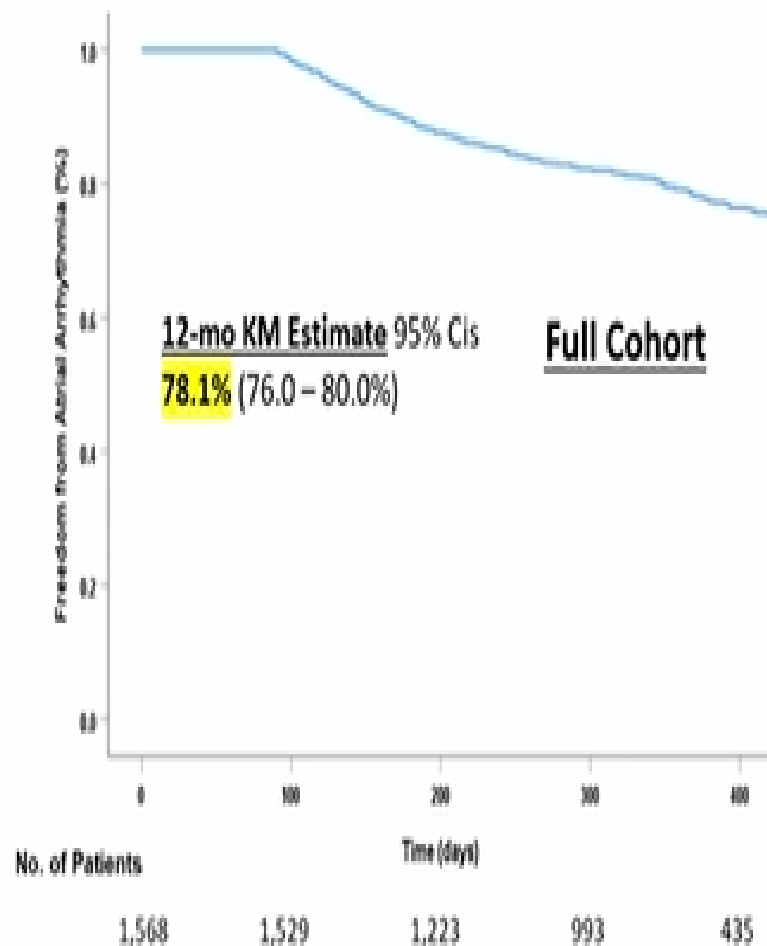
Fig. 2 Procedural efficiency and safety outcomes in pulsed field ablation versus thermal ablation of atrial fibrillation





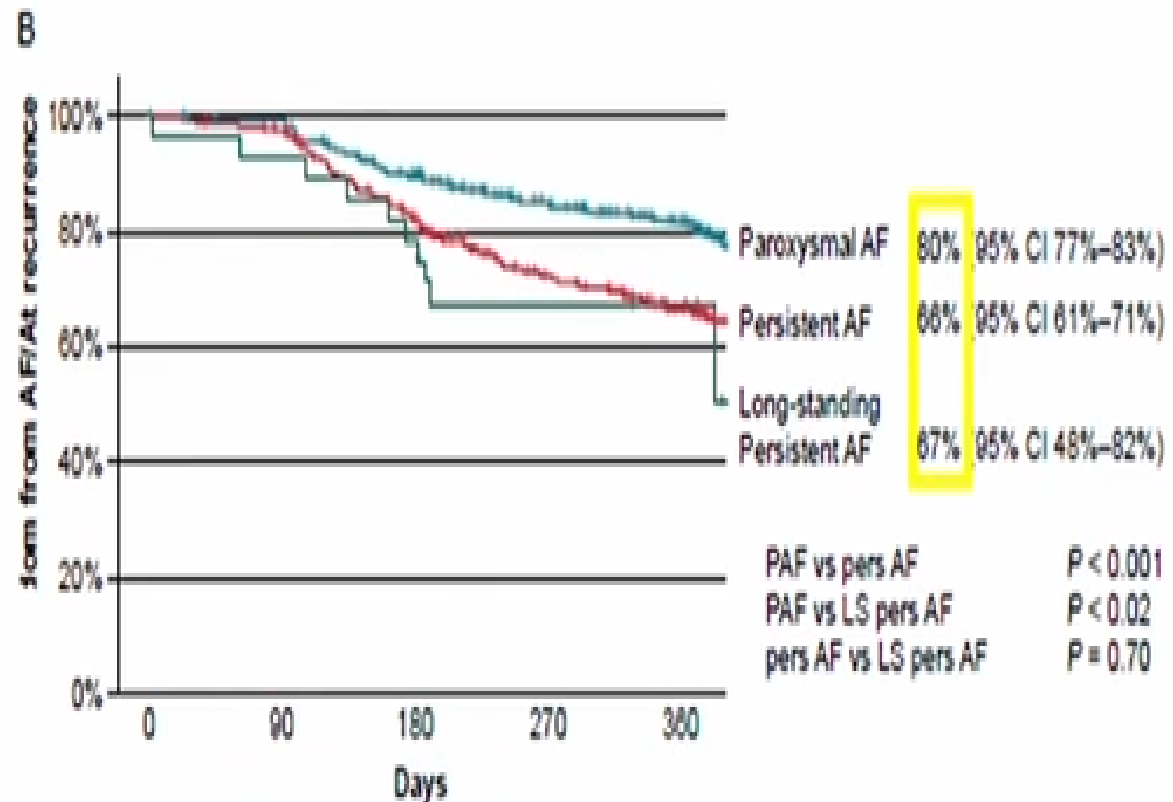
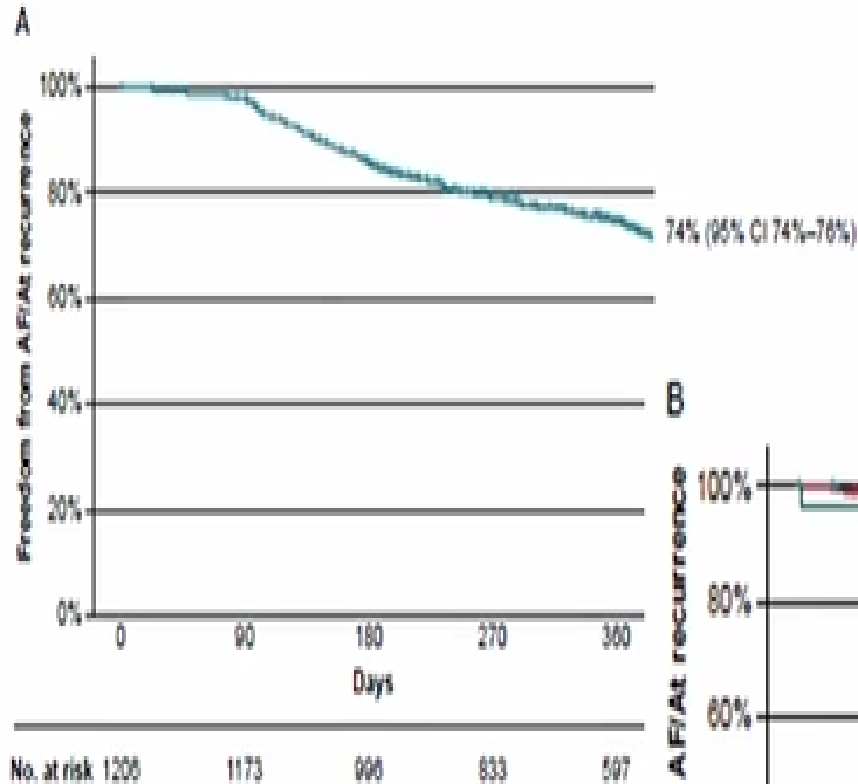
# Manifest PF : declarative survey (center-level data)

## Kaplan-Meier Analysis: Freedom from AF/AFL/AT



No. of Patients	1,021	995	800	657	282
Paroxysmal AF					
Persistent AF	547	524	414	336	153

# EUPORIA : Retrospective declarative survey

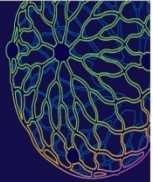


Schmidt B et al. *Europace*  
2023;25:1-11.

# Affera™ Mapping and Ablation System with Sphere-9™ Catheter

Novel, all-in-one system was noninferior in safety and delivered higher effectiveness outcomes

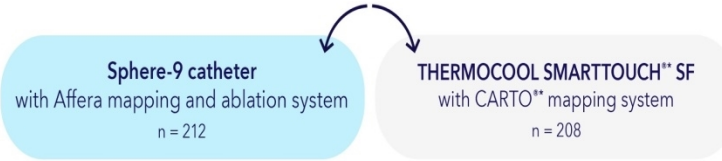
Caution: The Affera ablation system and Sphere-9 catheter are not approved by the FDA and not for sale in the U.S.



## SPHERE Per-AF clinical IDE

### Trial design and study population

- A pivotal, randomized, noninferiority trial
- Symptomatic, drug refractory or intolerant PerAF patients
- PVI plus additional linear lesions as needed

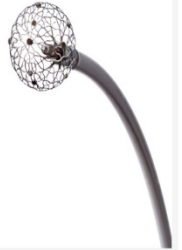


## Affera Sphere-9 catheter

### All-in-one

### Map | Ablate | Validate

- High resolution, close-unipolar mapping
- PF and RF energy modes
- Wide-area, conformable tip



## Primary safety event rate

**1.4%** vs. 1% in the control arm

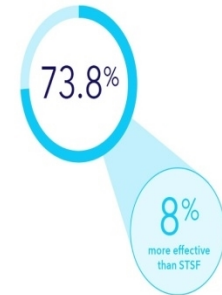
- 0 PV stenosis
- 0 Phrenic nerve paralysis
- 0 Cardiac tamponade
- 0 Atrio-esophageal fistula

**95.3%** Procedures completed with a single transeptal puncture

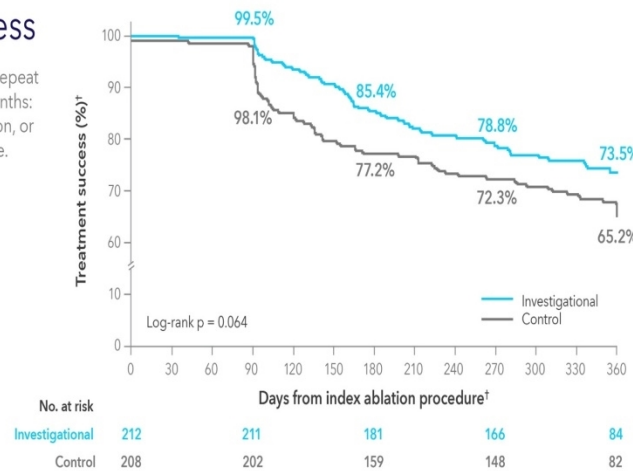
For a full list of safety events, review the SPHERE Per-AF manuscript.<sup>1</sup>

## Primary effectiveness

Defined as: Acute procedure failure, repeat ablation at any time, or after three months: recurrence of AF/AFL/AT, cardioversion, or new/re-initiated/increased AAD usage.



† The Kaplan-Meier endpoint included early study exits that the primary effectiveness endpoint did not include.



## Procedural characteristic superiority

**25 min less** Superior skin-to-skin procedural time

**27 min less** Superior time between first and last application

**29 min less** Superior energy application time

1. Anter E, Mansour M, Nair DG, et al. Dual-energy lattice-tip ablation system for persistent atrial fibrillation: a randomized trial. *Nat Med.* 2024.

\*Third-party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic company. Printed in USA.

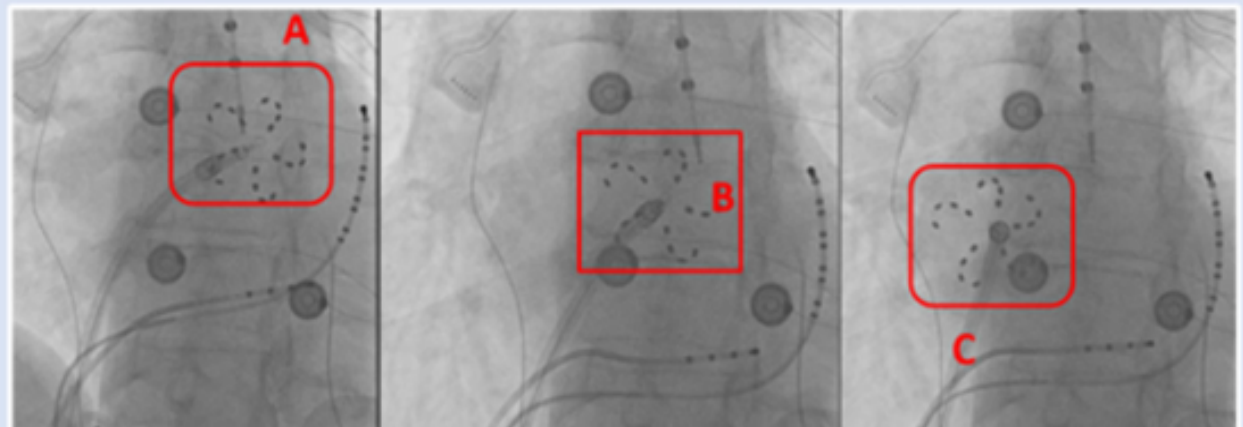
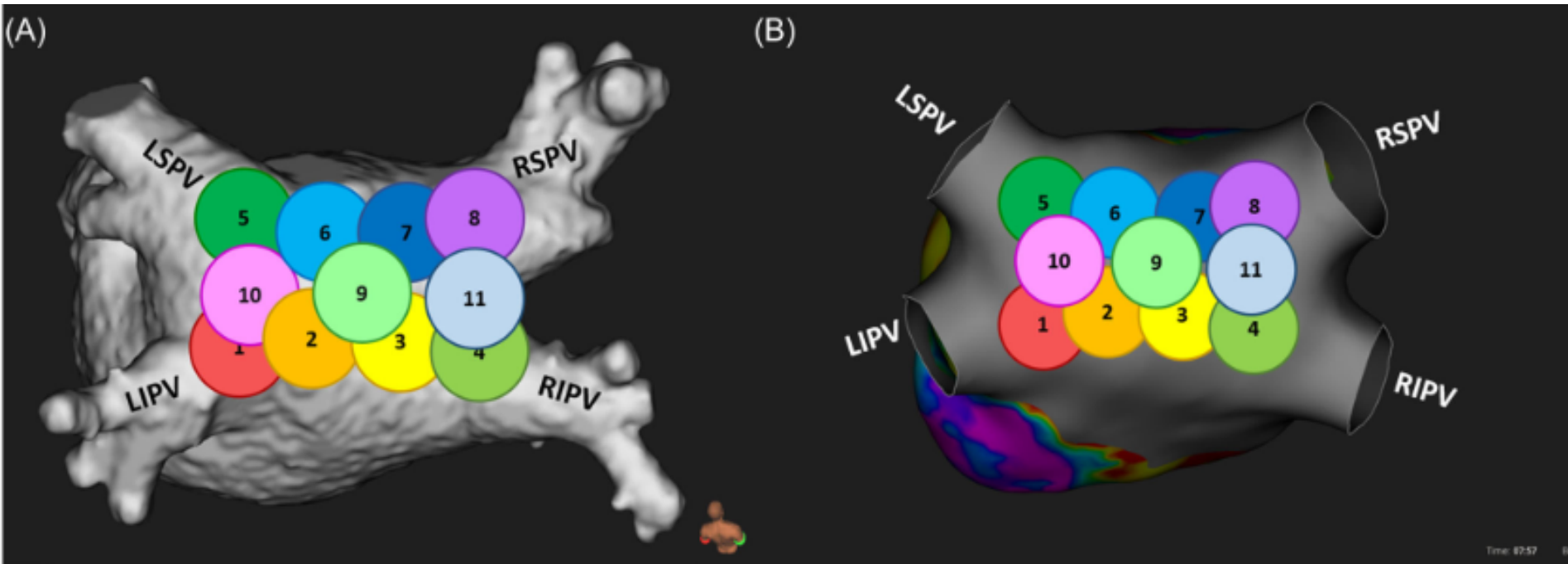
# ABLATION STRATEGY

Ablation strategies	Category of advice	Type of evidence
<b>Pulmonary vein isolation</b>		
Electrical isolation of the PVs is required during all AF ablation procedures	Advice TO DO	META <sup>236,238,241,243-245,247,248,253,294,304,566,622,788</sup>
Achievement of electrical isolation requires, at a minimum, assessment and demonstration of entrance block into the PVs	Advice TO DO	META <sup>236,238,241,243-245,247,248,253,294,304,566,622,788-792</sup>
A waiting period (e.g. 20 min) following initial PVI may be reasonable to monitor for PV reconnection	Area of uncertainty	RAND <sup>793-800</sup>
Administration of adenosine 20 min following initial PVI, with reablation if PV reconnection occurs, may be reasonable to improve PVI durability	Area of uncertainty	RAND <sup>794,796-798,801-807</sup>
Pace capture-guided approach following PVI using RF energy may be reasonable to improve PVI durability	Area of uncertainty	RAND <sup>808-810</sup>
<b>Adjunctive ablation targets beyond pulmonary vein isolation</b>		
If linear ablation lesions are deployed, mapping and pacing maneuvers are required to document conduction block	Advice TO DO	OBS <sup>811-818</sup>
If a reproducible focal trigger that initiates AF is identified outside the PV ostia at the time of an AF ablation procedure, ablation of the focal trigger is beneficial	Advice TO DO	OBS <sup>819-823</sup>
Vein of Marshal ethanol infusion is reasonable to facilitate achieving block in the lateral mitral isthmus in patients with mitral annular flutter	May be appropriate TO DO	OBS <sup>196,824-826</sup>
Ablation of areas of abnormal myocardial tissue identified with voltage mapping during sinus rhythm may be reasonable during persistent AF ablation	Area of uncertainty	META <sup>827-829</sup>
Vein of Marshal ethanol infusion may be reasonable during persistent AF ablation	Area of uncertainty	RAND <sup>830-834</sup>
Mapping and ablation of non-PV triggers may be reasonable during persistent AF ablation	Area of uncertainty	OBS <sup>819-823,835</sup>
Isolation of the left atrial posterior wall may be reasonable during repeat ablation of persistent AF	Area of uncertainty	META <sup>836-847</sup>
Ablation of MRI-detected atrial delayed enhancement areas is not beneficial during persistent AF ablation <sup>8</sup>	Advice NOT TO DO	META <sup>848,849</sup>

# Pulsed field ablation technology for pulmonary vein and left atrial posterior wall isolation in patients with persistent atrial fibrillation

SCHIAVONE ET AL.

Cardiovasc Electrophysiol. 2024 Jun;35(6):1101-1111.





# Impact of Left Atrial Posterior Wall Ablation During Pulsed Field Ablation for Persistent Atrial Fibrillation: A MANIFEST-PF Registry Substudy

MANIFEST-PF population  
N = 1,568

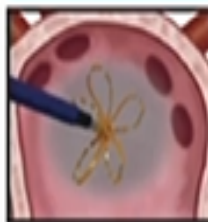
Pers-AF cohort  
N = 547

PV isolation

PV isolation +  
LAPW ablation  
N = 131

PV Isolation

LA Posterior Wall  
Ablation



## Population

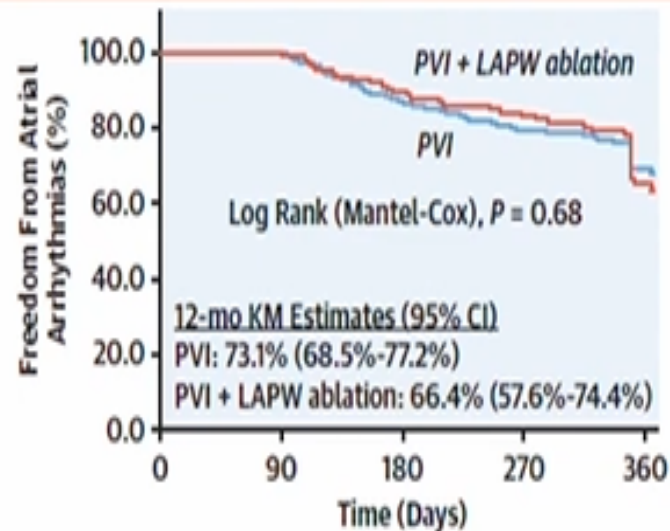
Adults with PersAF undergoing first-time AF ablation using pulsed-field  
Mean age: 66.3 years

## Locations

24 centers from 8 countries

## Primary Outcome

Freedom from any atrial arrhythmia of  $\geq 30$  seconds with or without antiarrhythmic drugs, after a single ablation procedure



## No. of Patients

PVI + LAPW ablation	131	130	112	101	65
PVI	416	413	326	256	167

- PVI+ patients were younger, with lower CHADVASC2 score, more likely to receive 3D mapping

- Same results in the propensity-matched cohorts

Turagam MK et al. JACC EP. 2024;10(5):900-912

# Pulsed-Field Ablation on Mitral Isthmus in Persistent Atrial Fibrillation: Preliminary Data on Efficacy and Safety

Baptiste Davong <sup>1</sup>, Raquel Adeliño <sup>1</sup>, Hubert Delasnerie <sup>1</sup>, Jean-Paul Albenque <sup>1</sup>,  
Nicolas Combes <sup>1</sup>, Christelle Cardin <sup>1</sup>, Quentin Voglimacci-Stephanopoli <sup>1</sup>, Stéphane Combes <sup>1</sup>,  
Serge Boveda <sup>2</sup>

Complete MI block:100%

Coronary spasm :4.4%

Recurrence rate : 20%

# Multielectrode catheter-based pulsed field ablation of persistent and long-standing persistent atrial fibrillation

PerAF>6mo and LSPAF patients (n = 72)

**3-stage protocol**

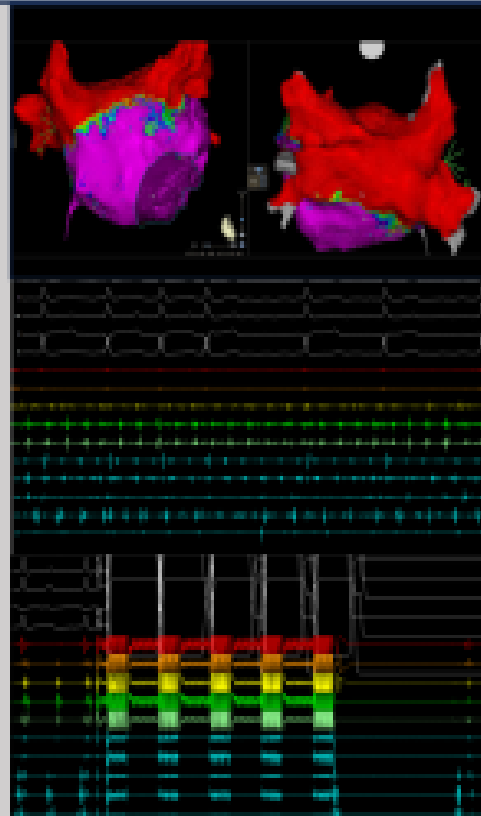
**Stage 1:** PV antral and PW isolation



**Stage 2:** EGM-guided substrate ablation



**Stage 3:** AT regionalization and ablation



➤ Procedural time:  
112 ± 25 min

➤ AF termination: 95.8%

➤ 12-mo arrhythmia-free survival >80%



# EXTRA PV SETS: OFF LABEL

## Manifest PF: declarative survey

Procedural characteristics	Never	Sometimes	Frequently	Always
Additional lesion sets				
Roof line (%)	50	25	12.5	12.5
Lateral mitral isthmus line (%)	62.6	33.2	4.2	0
Left atrial posterior wall (%)	25	45.8	16.7	12.5
Anterior line (%)	75	25	0	0
SVC isolation (%)	95.8	4.2	0	0
CFAE (%)	95.8	4.2	0	0
LAA isolation (%)	93.8	6.2	0	0
Non-PV trigger (%)	79.2	20.8	0	0

## EUPORIA : Restrospective declarative survey

Parameter	N = 1233
PVI only ablation, n (%)	1064 (86)
Extra-PV ablation	169 (14)
Posterior wall isolation, n (%)	127 (10)
LA isthmus ablation, n (%)	62 (5)
Cavo-tricuspid isthmus ablation, n (%)	6 (0.5)

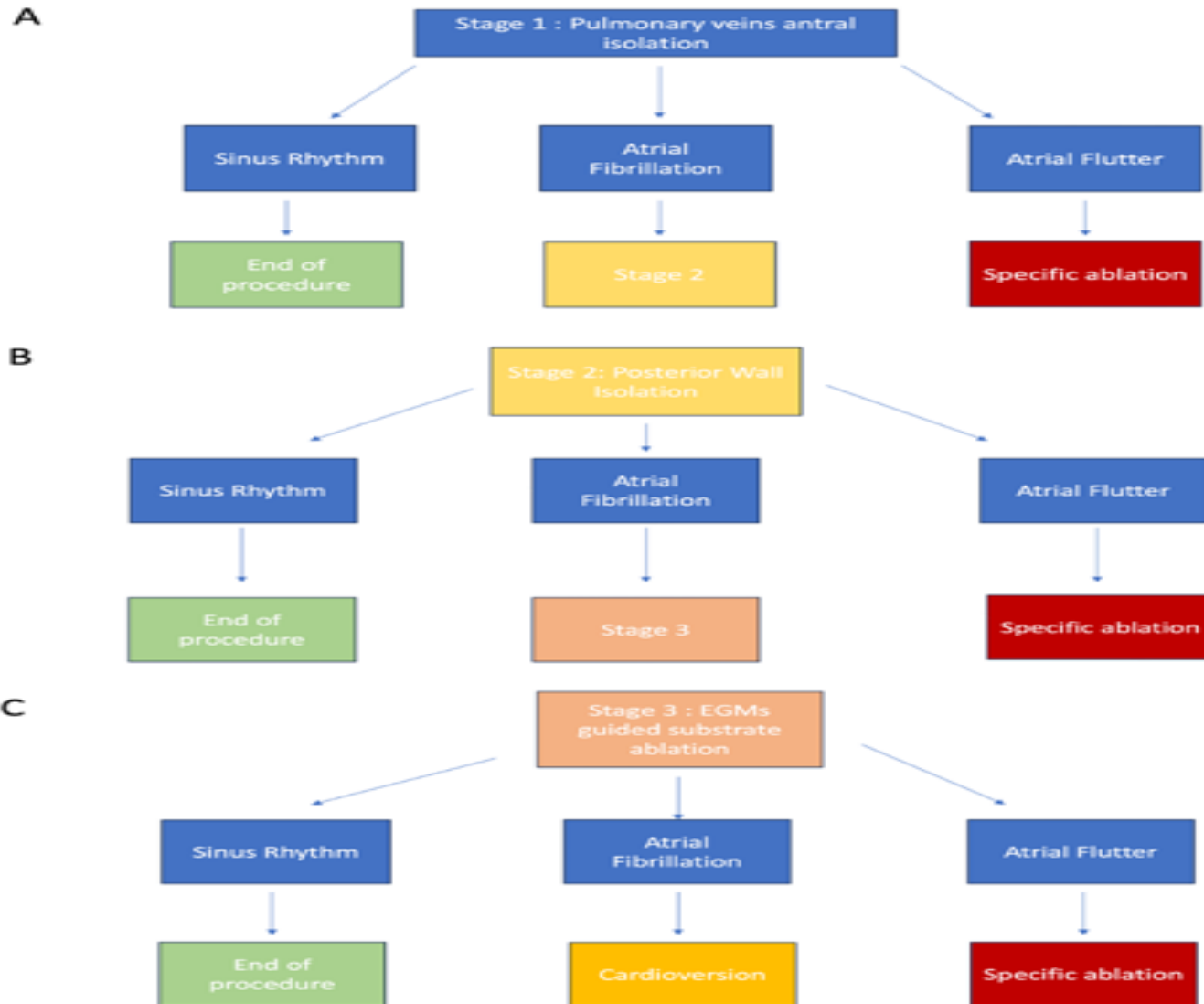
## FRANCE PFA: Exhaustive Nationwide registry

Parameters	Value
	Mean ± SD or N (%)
PVI only ablation (overall)	3380 (64.7%)
PVI only ablation (paroxysmal AF patients)	2285 (82.7%)
PVI only ablation (persistent AF patients)	845 (44.5%)
PVI only ablation (LS persistent AF patients)	85 (26.6%)
PVI only ablation (unknown type of AF)	165 (68.8%)
Additional lesion sets	
Roof line	999 (19.1%)
N° of PFA applications	11 ± 6
Mitral isthmus line	514 (9.8%)
N° of PFA applications	17 ± 12
Left atrial posterior wall	1335 (25.6%)
N° of PFA applications	16 ± 8
Cavotricuspid isthmus	145 (2.8%)
Superior Vena Cava	144 (2.7%)

# THE MAP AND ABLATE PFA CATHETER CONCEPT

- All-in-one tool/Map and ablate
- No exchanges
- Make use high density and know advanced mapping capabilities
- Perform VP isolation
- Perform linear lesions
- Perform ablation substrate
- No risk of AE fistula/phrenic injury/pv stenosis

# MY APPROACH WITH SPHERE



# Clinical Case

70 year old man Background HTA persistent AF, failed cardioversion, not responding to amiodarone, FEVI 40%, LA 190ml.

## Treatment

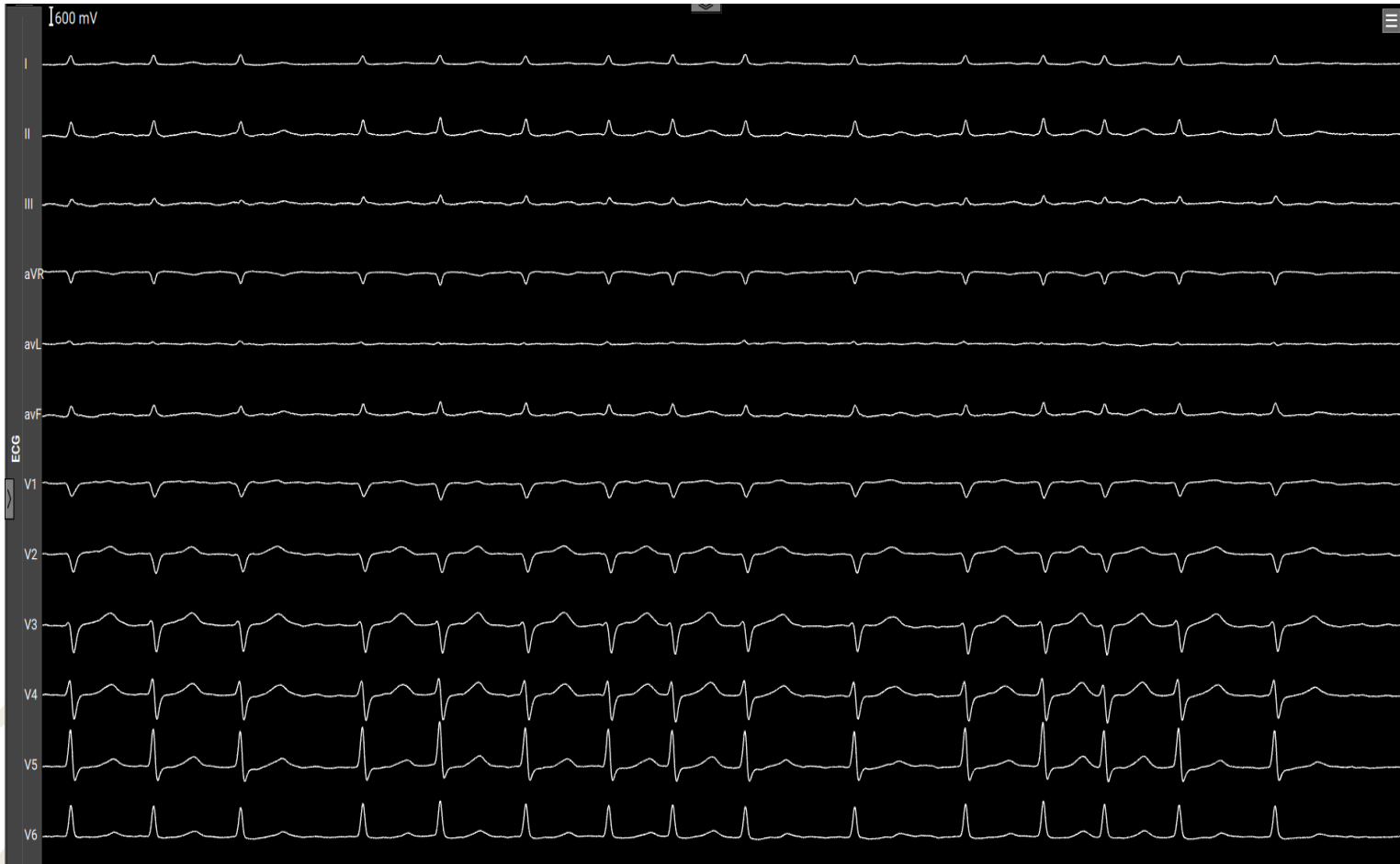
Apixaban 5 mg/12h

Ramipril 10mg/24h

Bisoprolol 5mg/24h

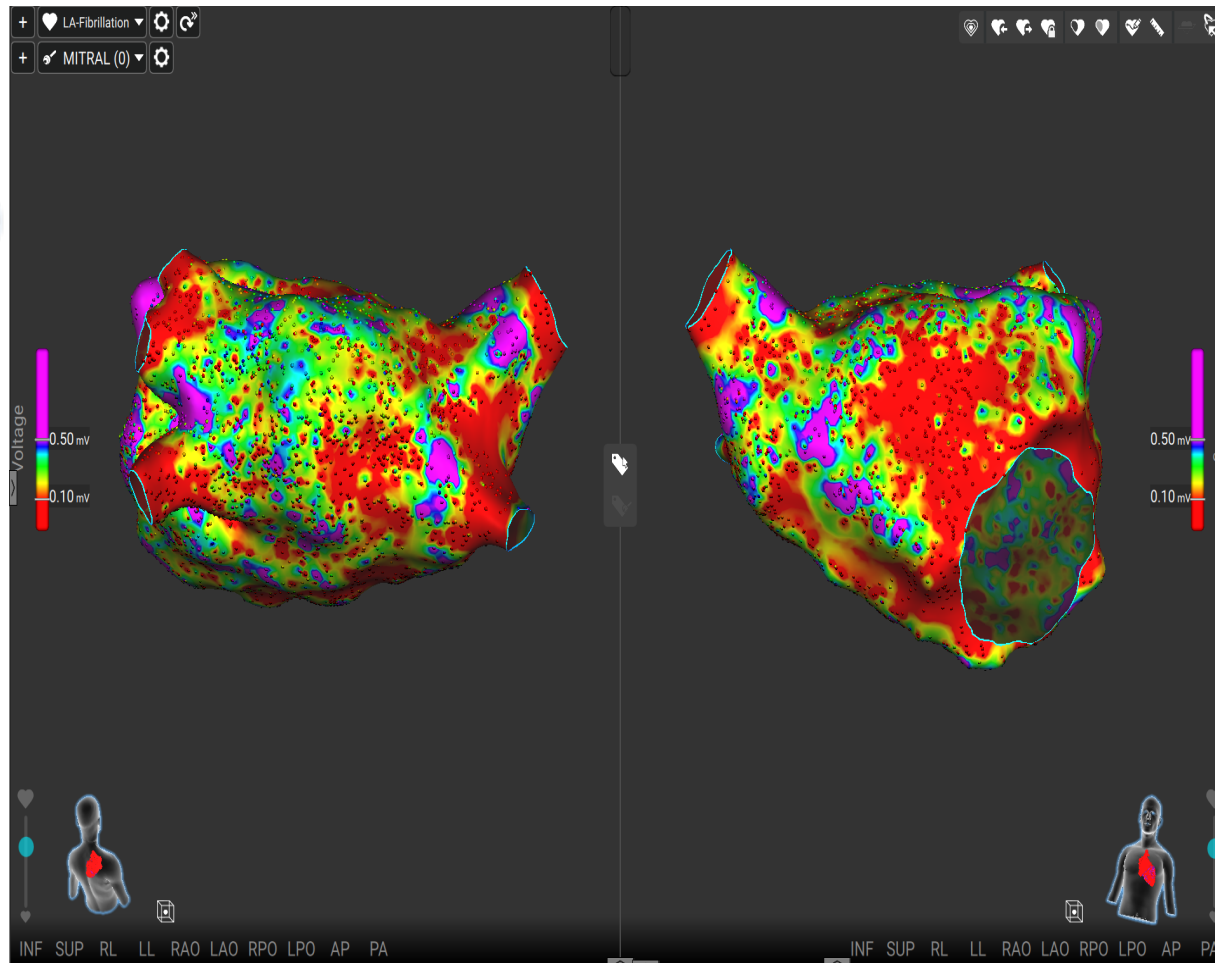
# Starting ECG

- Patient arrived in AF

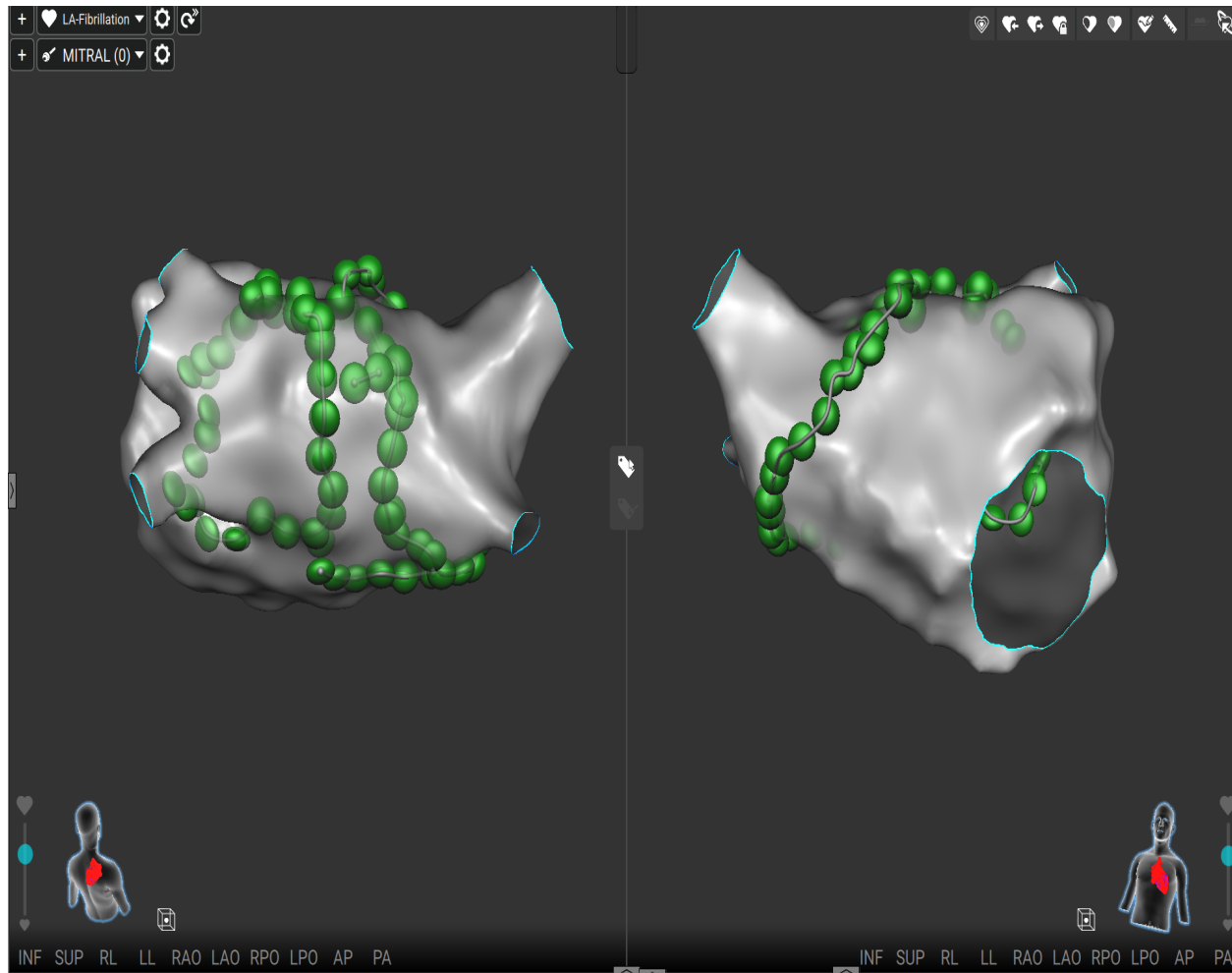


# AF mapping of the left atrium

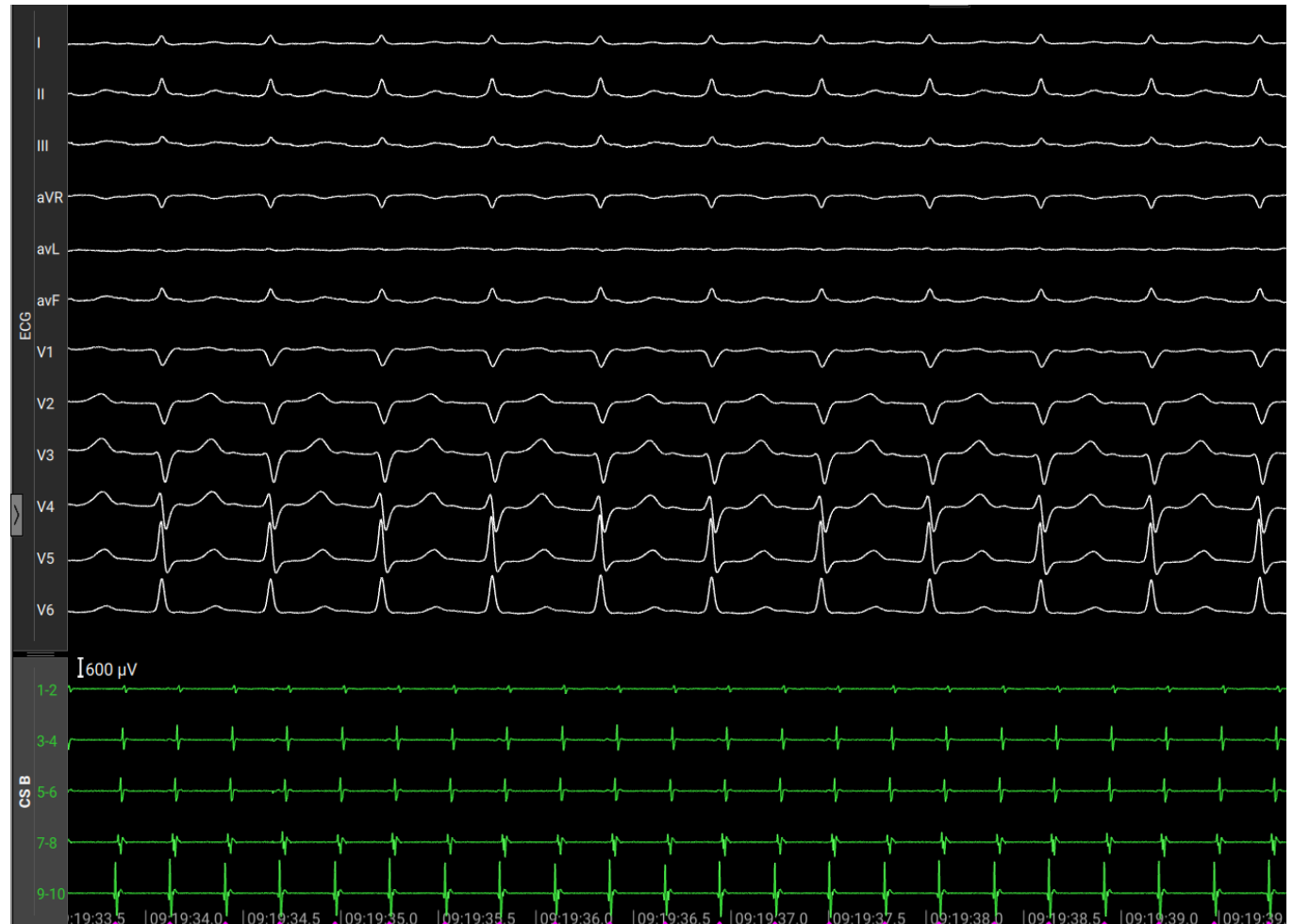
- Patient arrived in AF



# Pulmonary vein isolation (PVI) and box ablation in PFA



# Transition to tachycardia of 295 ms in the left atrium during remapping post PVI + box ablation

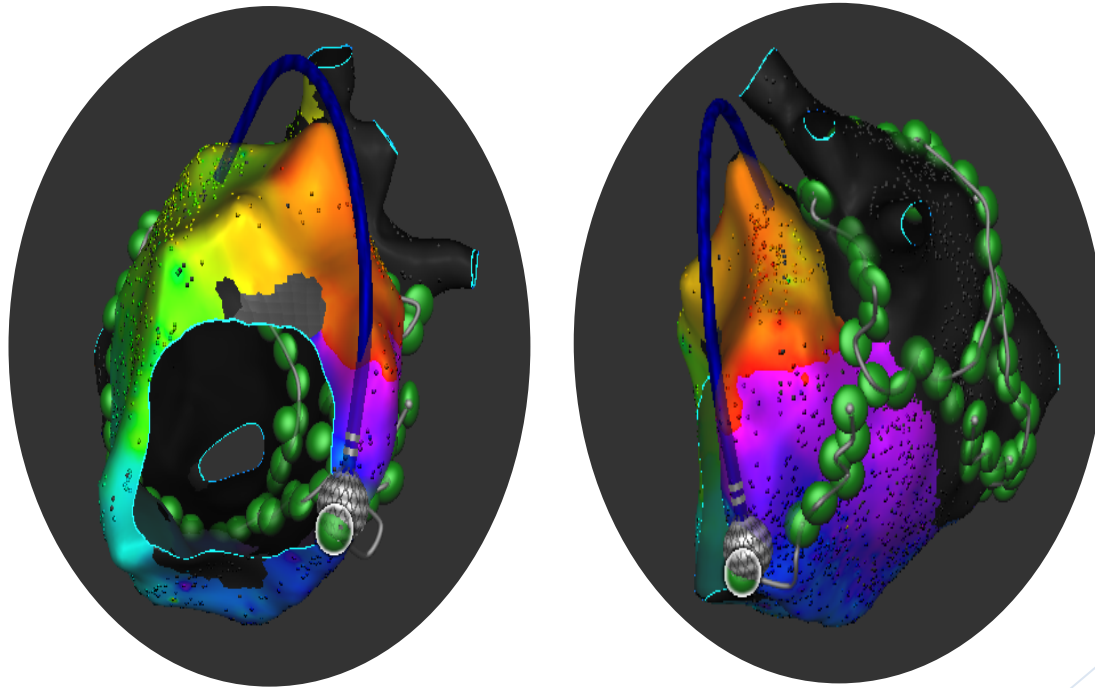


Tachycardia organized  
with a cycle length of  
295 ms

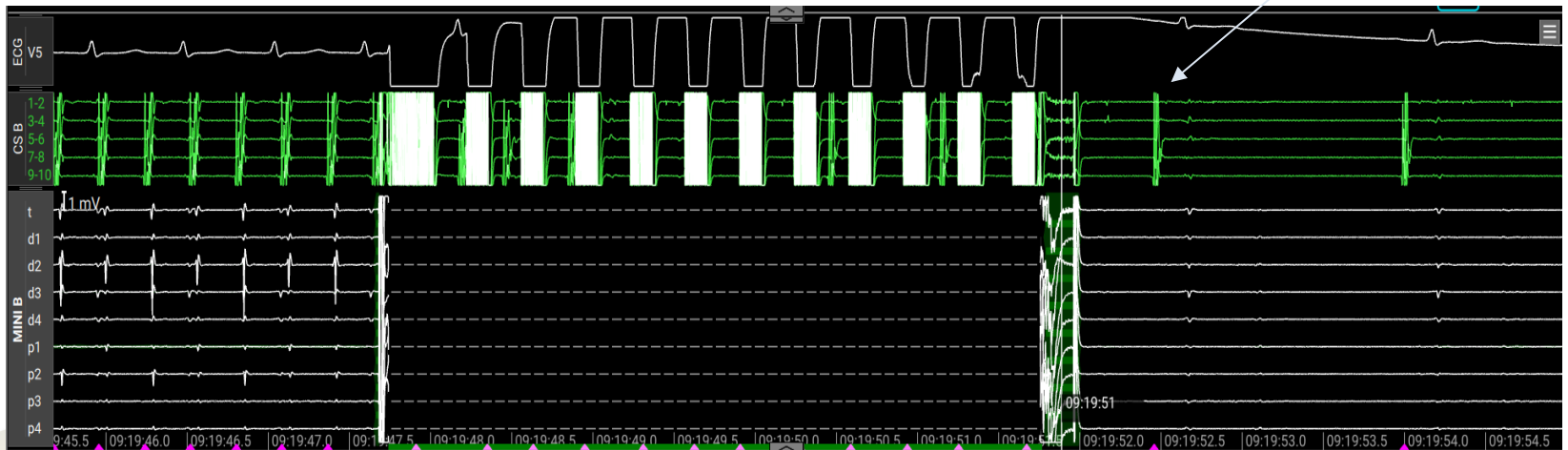
*CS 9-10 before CS  
1-2*



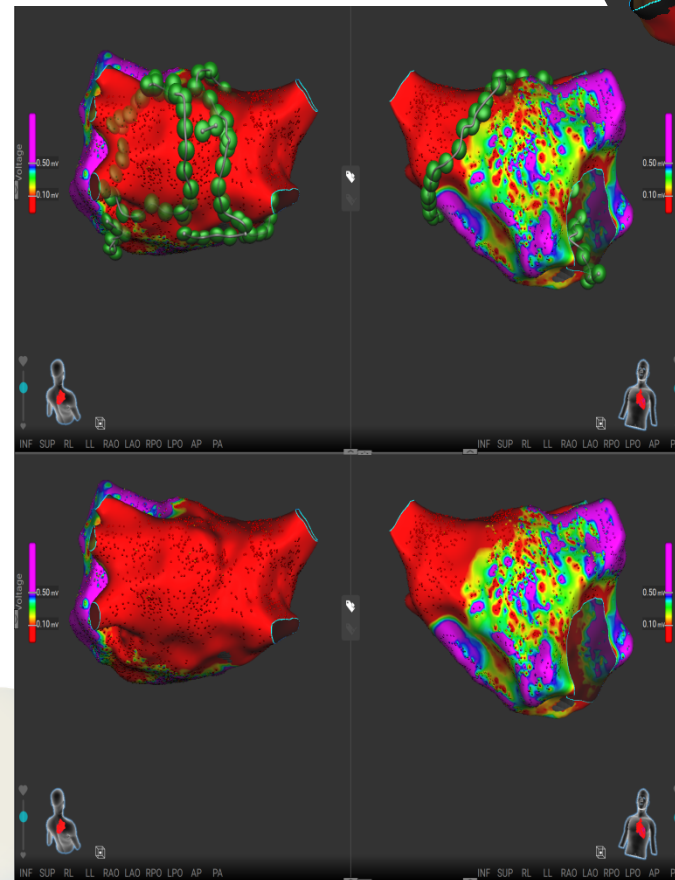
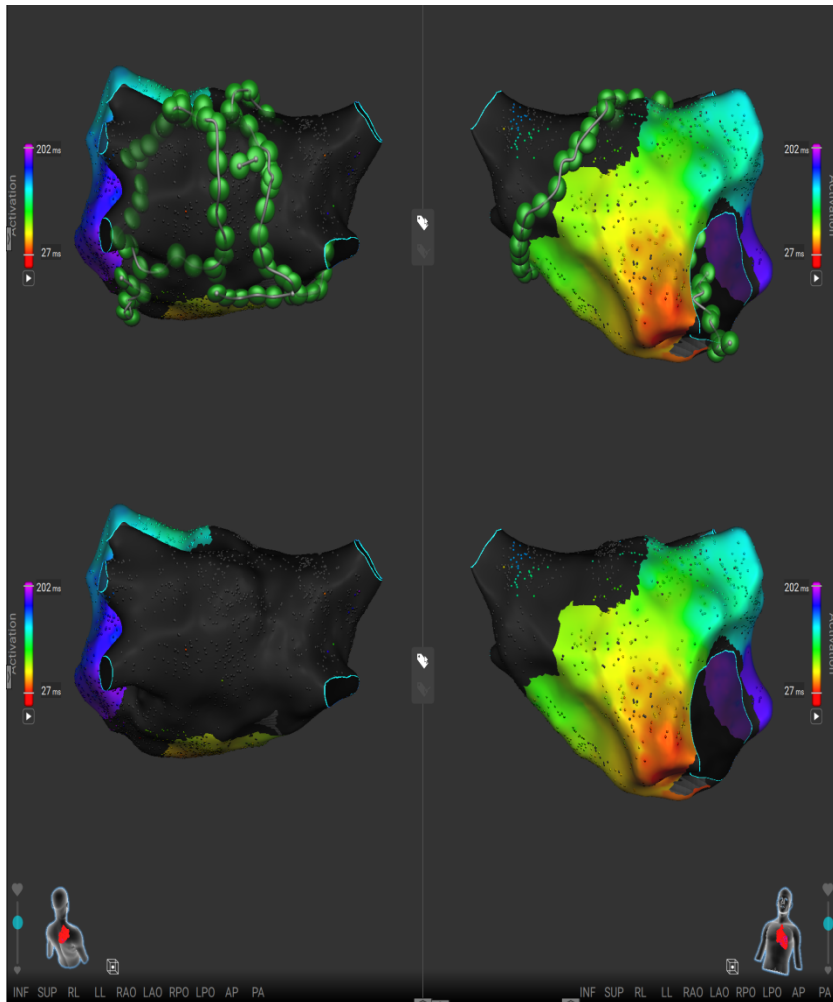
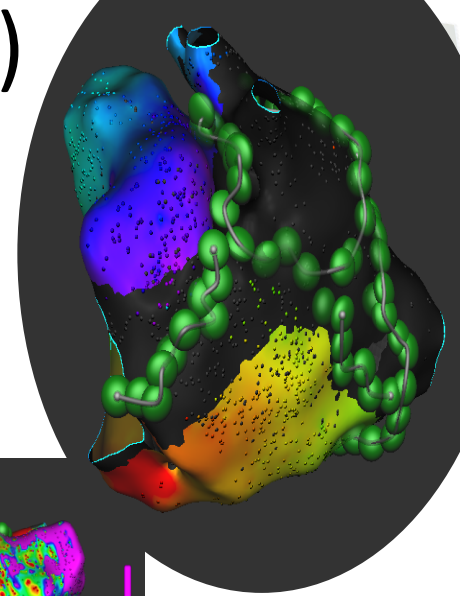
# Mitral isthmus ablation in PFA



Sinus return



# Mapping (with a pace from CS 9-10) of the left atrium post PVI + box + mitral isthmus



# Clinical Case

63 year old women background HTA and long-standing persistent AF, failed cardioversion, not responding to amiodarone, FEVI 50%, LA 170ml.

## Treatment

Apixaban 5 mg/12h

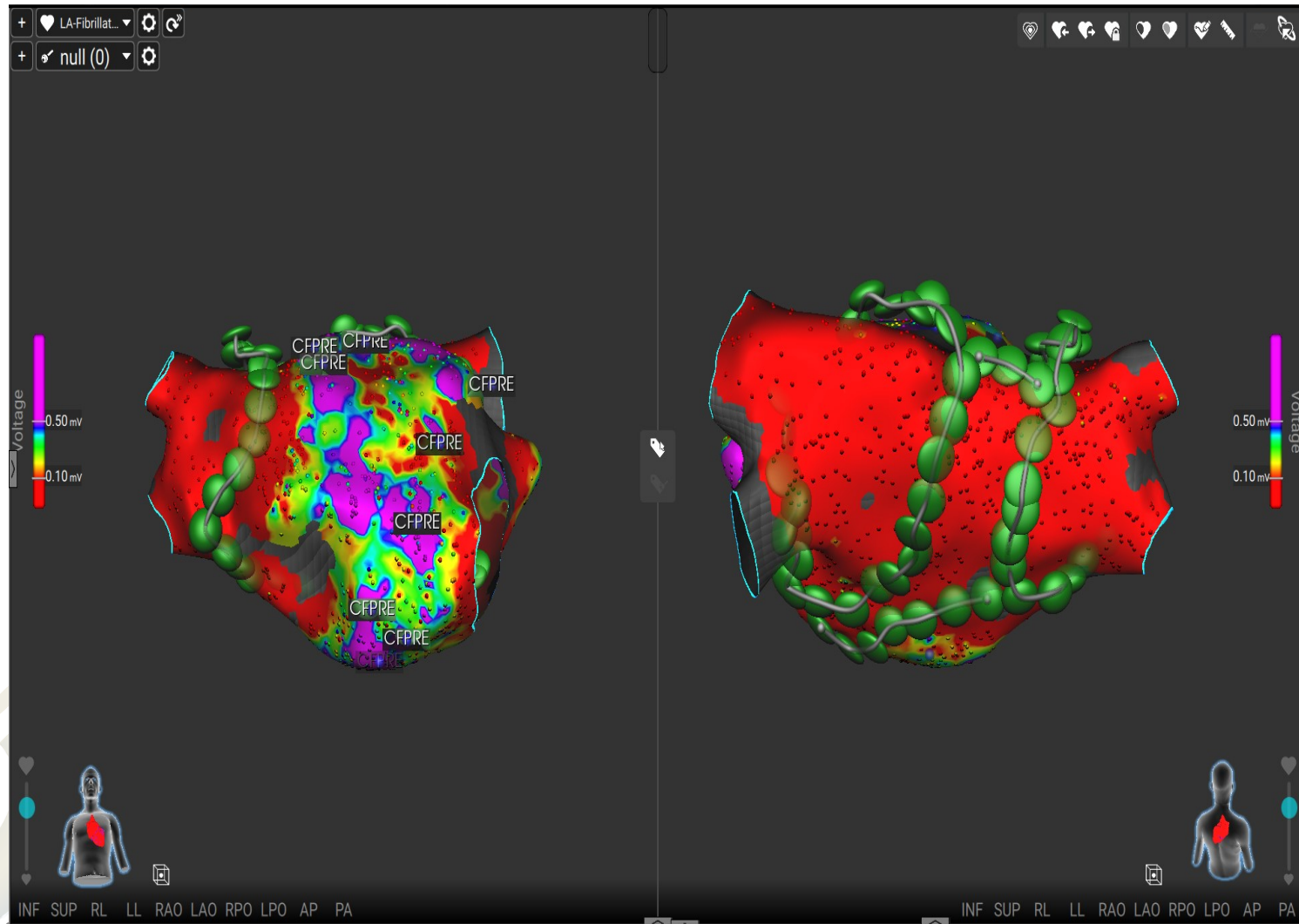
Ramipril 10mg/24h

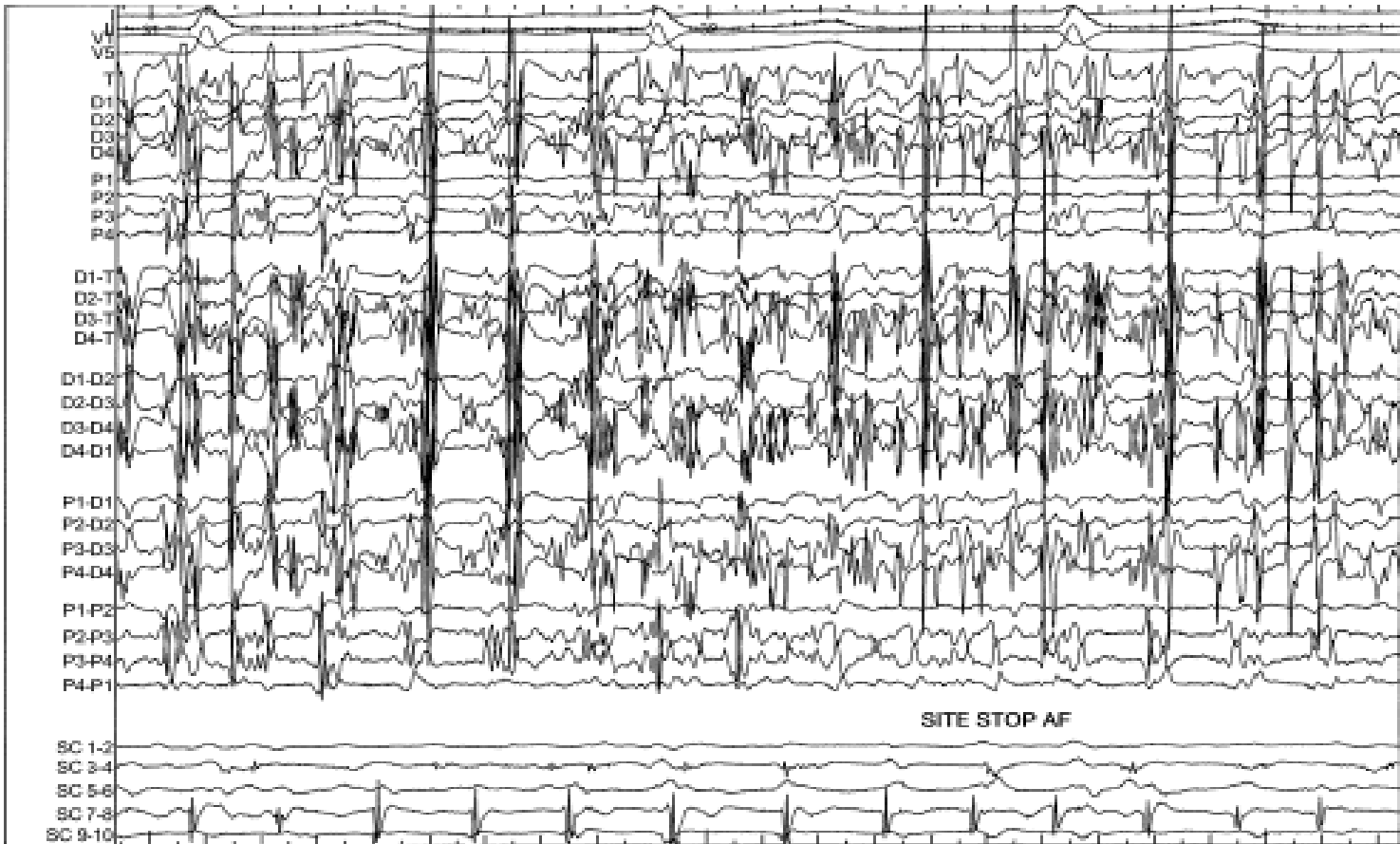
Bisoprolol 5mg/24h

Eupressyl 30/24h

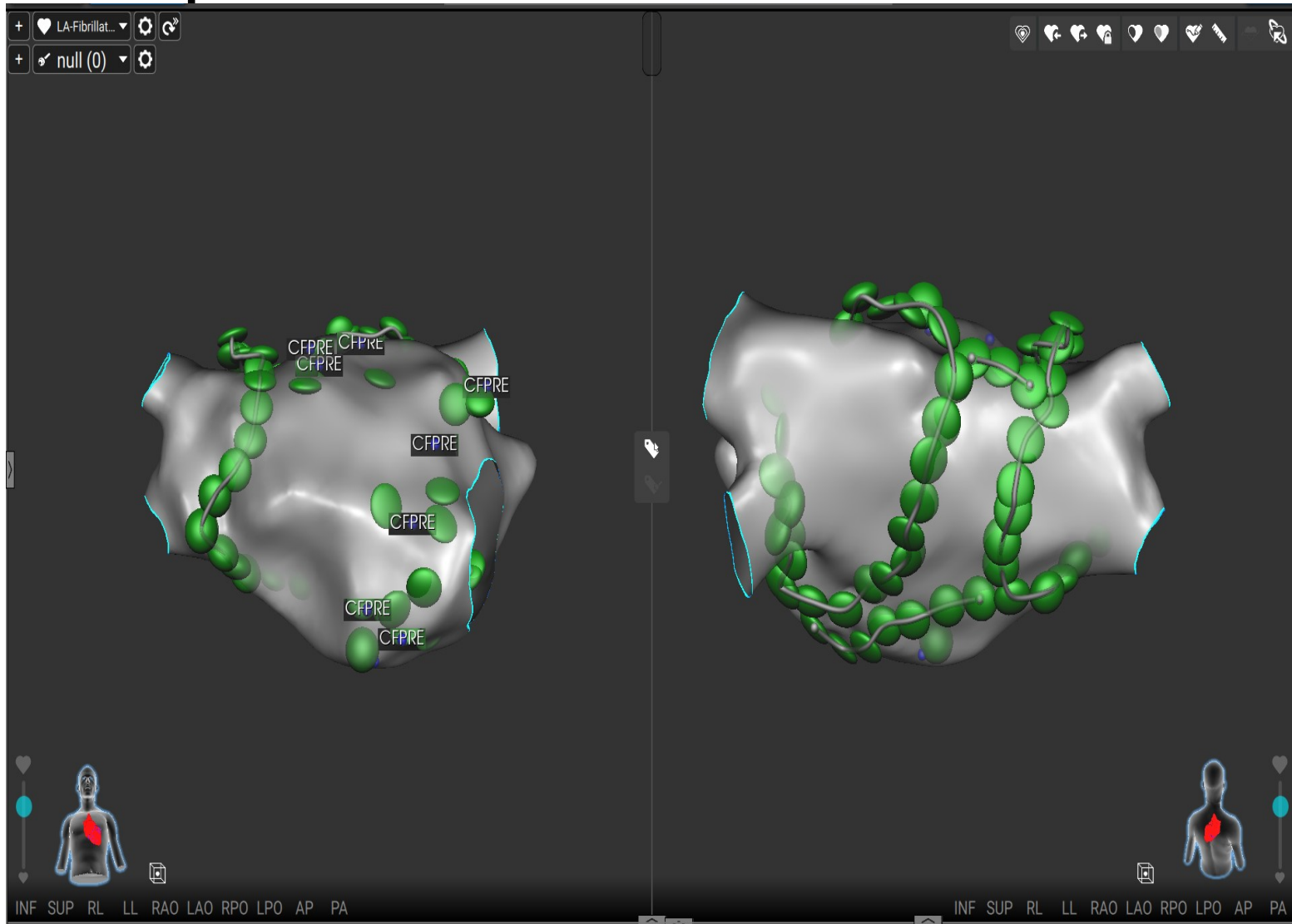
Zopiclone 7.5/24h

# AF remapping of the left atrium post PVI + box ablation and identification of dispersion

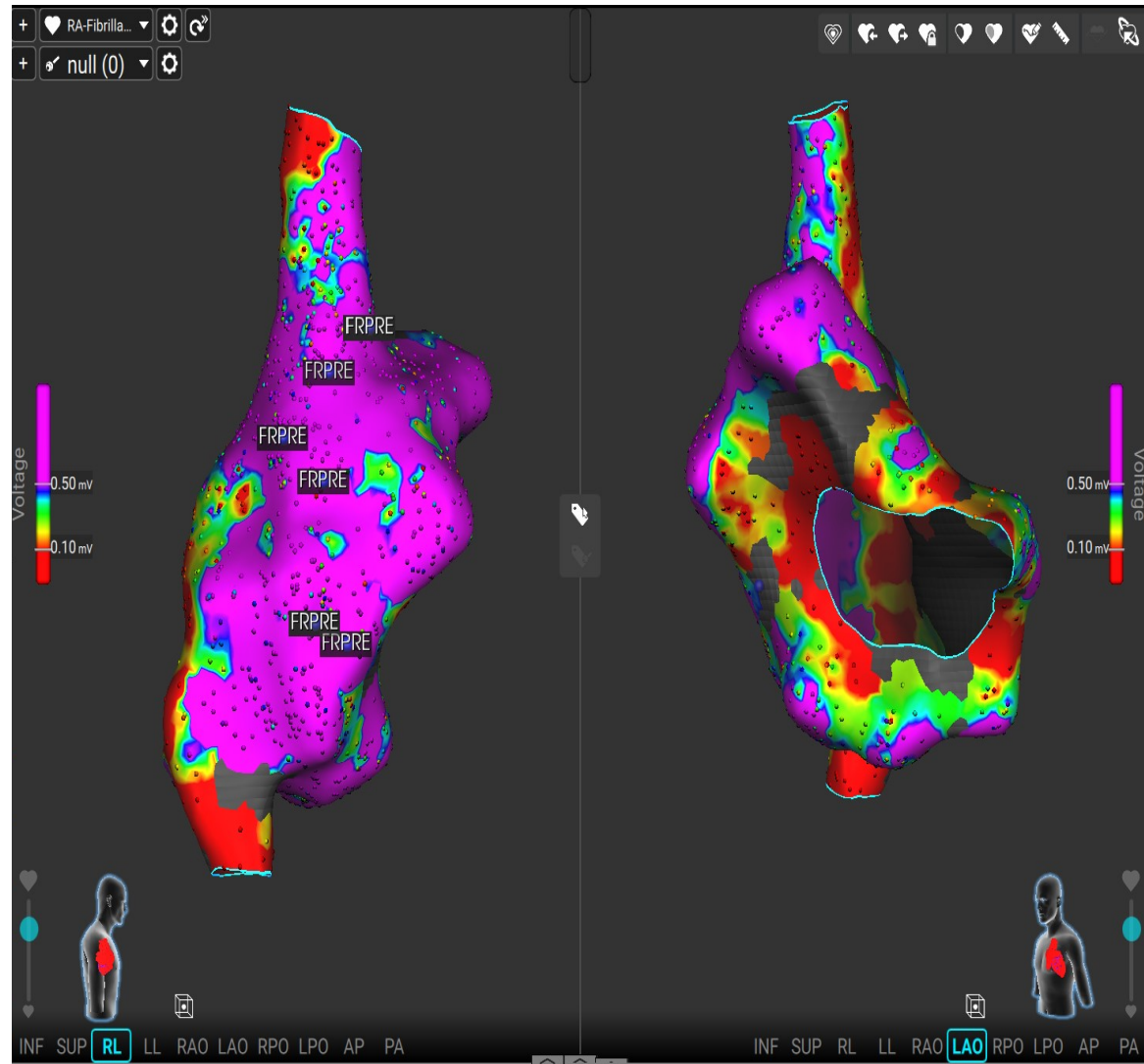




# Dispersion zones ablation in PFA



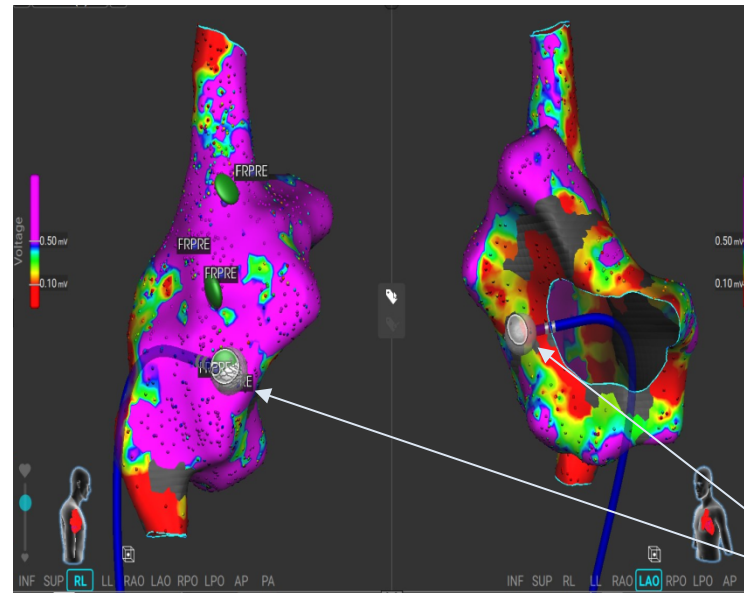
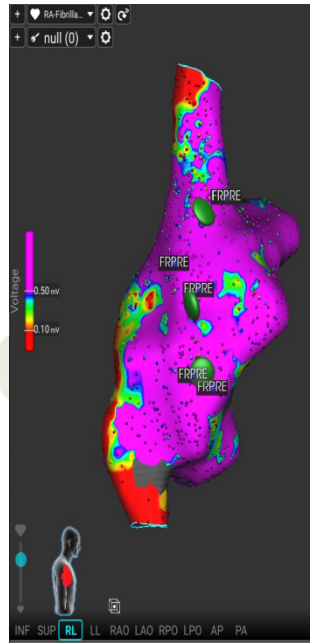
# AF mapping of the right atrium and identification of dispersion zones



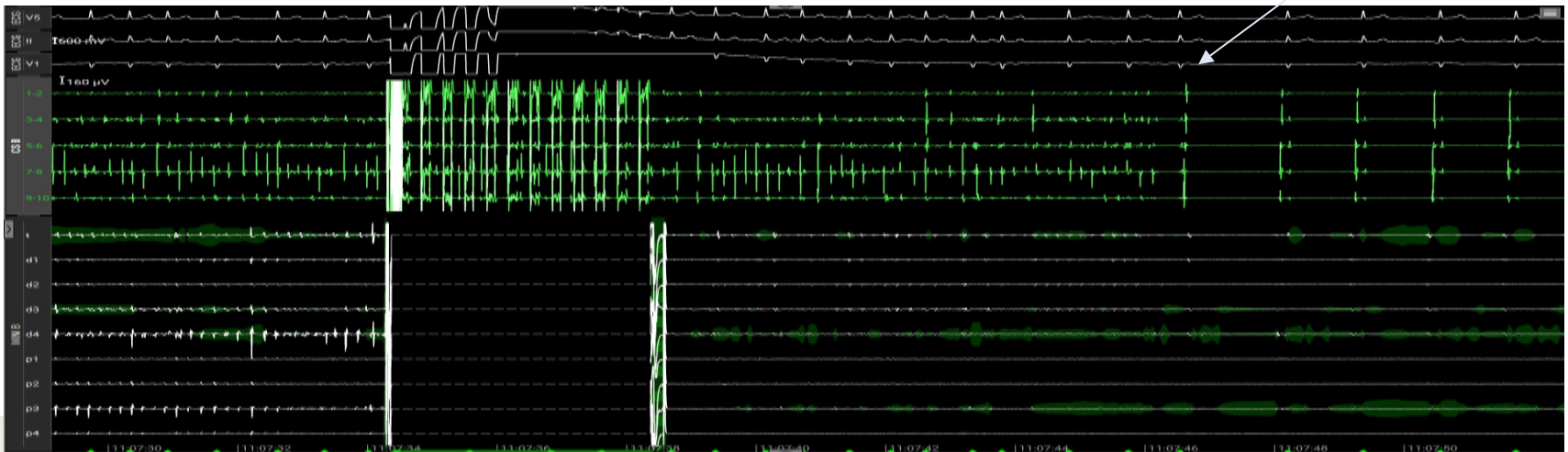


# Dispersion zones ablation in PFA in the right atrium

All ablation shots in the right atrium



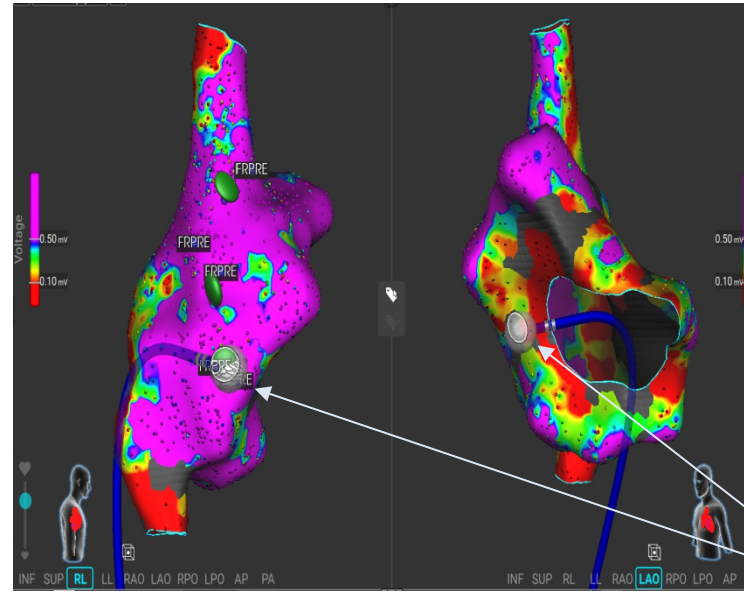
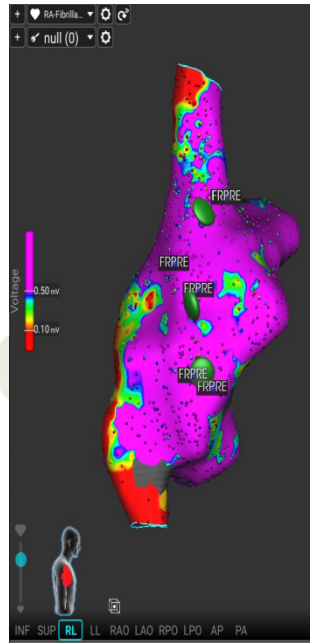
Sinus return after ablation of an identified dispersion zone



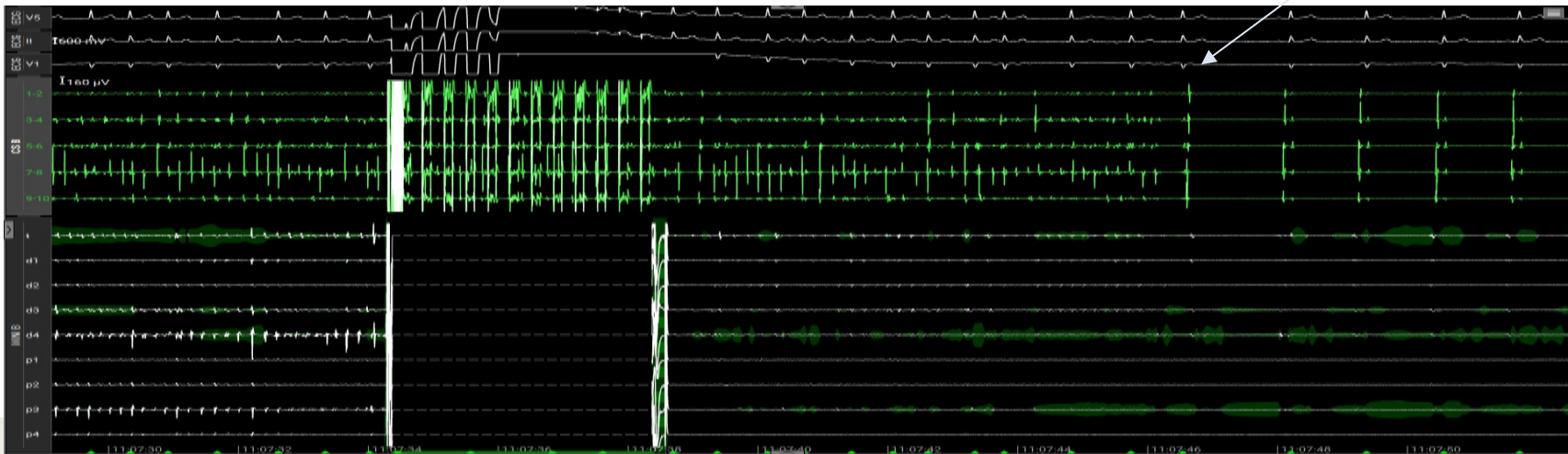


# Dispersion zones ablation in PFA in the right atrium

All ablation shots in the right atrium



Sinus return after ablation of an identified dispersion zone



# Clinical Case

43 year old man ,persitent AF FEVI 62%, LA  
130ml.

Ablation AF2022 Farapulse pvi

Ablation2023 Marshall(vp+roof+ethanol+MI)

Ablation 2023 Roof+MI

Treatment

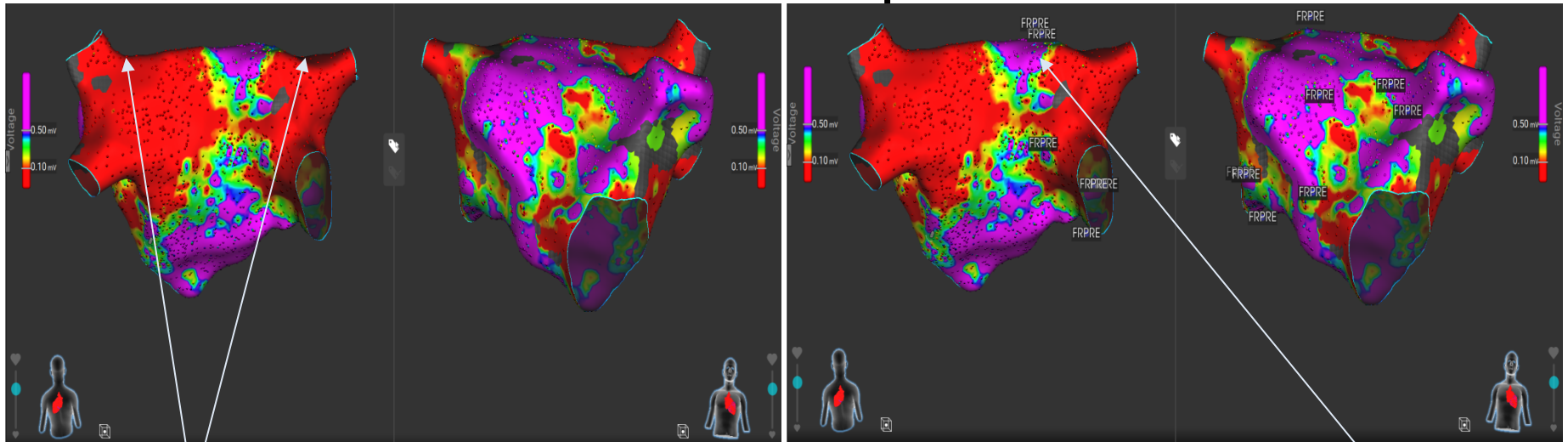
Apixaban 5 mg/12h

# Starting ECG

- Patient arrived in AF

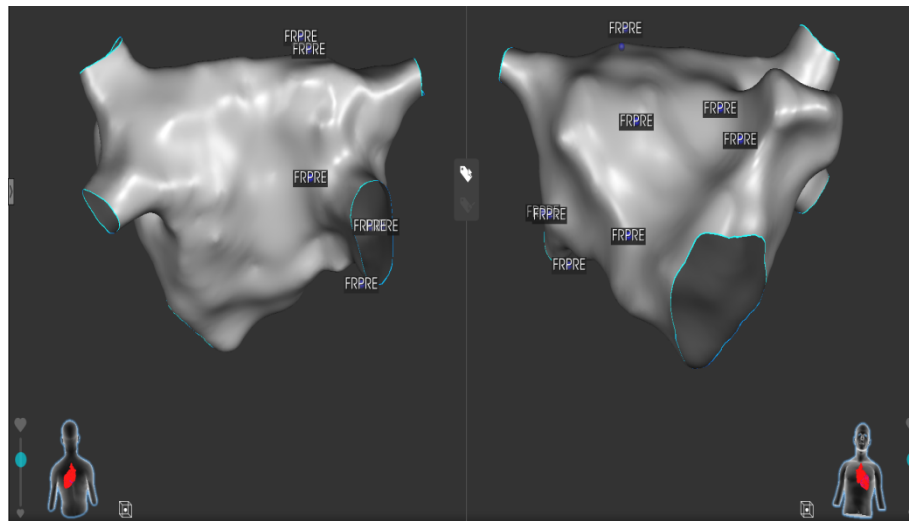


# AF mapping of the left atrium (post PVI + roof + mitral ablation + Marshall alcolization) and identification of dispersion zones



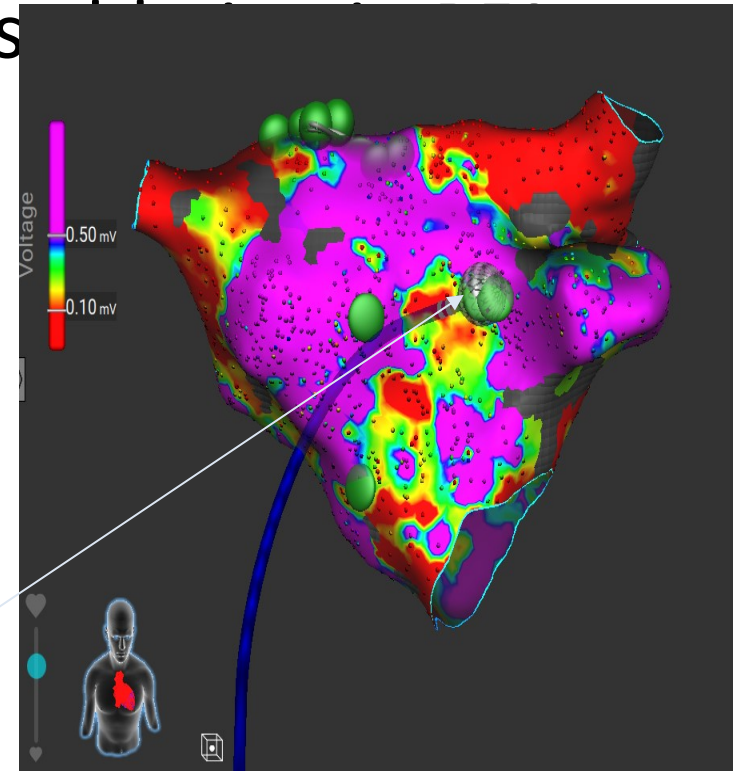
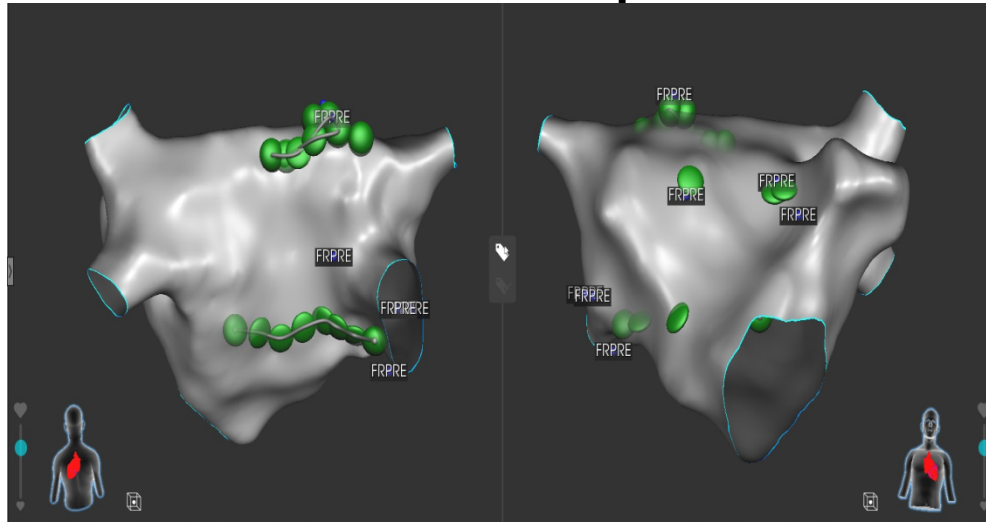
Veins still isolated

Posterior wall connected

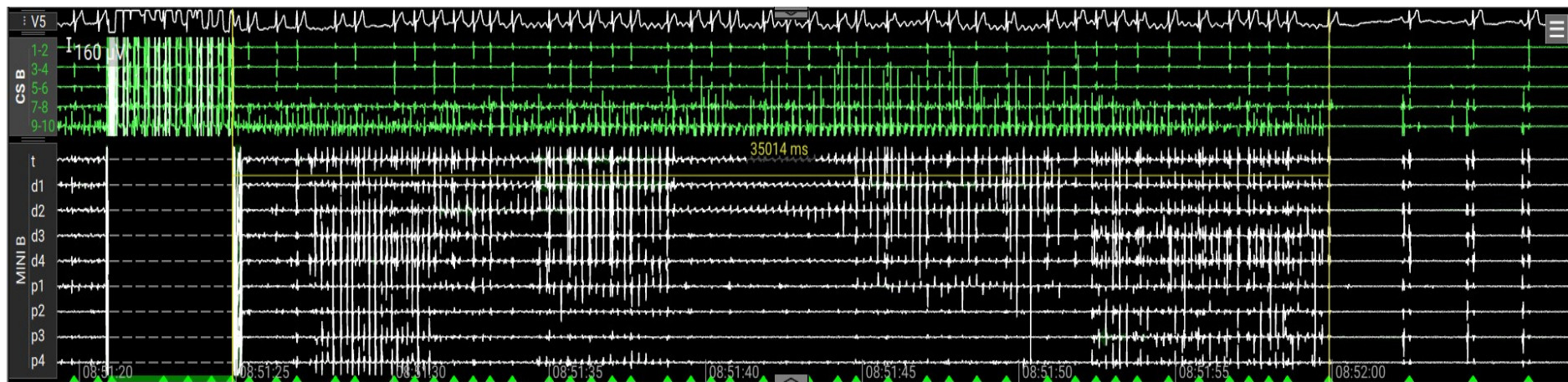




# Box and dispersion zones



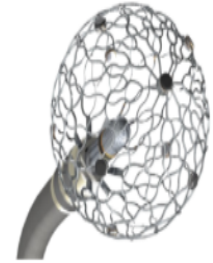
Sinus return in 35 seconds after ablation of an identified dispersion zone



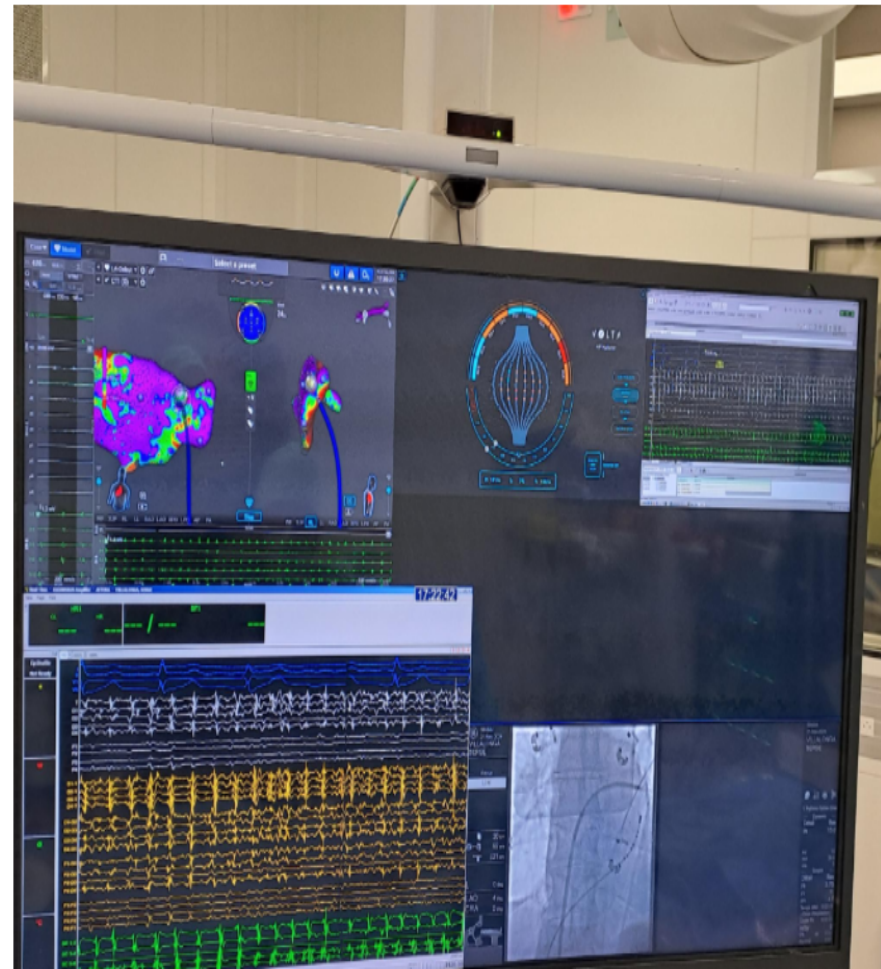
## Results: Procedural Characteristics

Characteristic	Tailored (N=187)	Anatomical (N=183)	<i>p</i> -value
Procedure time (min)	178 ± 60	92 ± 36	P < 0.001
3D nav ± AI mapping	31 ± 22	10 ± 5	P < 0.001
Additional Mapping Time (e.g. for AT)	17 ± 15	n.a.	n.a.
Fluoroscopy time (min)	9 ± 10	5 ± 4	P < 0.001
Total RF time (min)	42 ± 17	20 ± 11	P < 0.001
<b>Acute atrial fibrillation termination by ablation – no. (%)</b>	<b>122/186 (66)</b>	<b>26/169 (15)</b>	<b>P &lt; 0.001</b>
Acute sinus rhythm conversion by ablation – no. (%)	100/187 (53)	23/172 (13)	P < 0.001

# Persistent AF Case Presentation (Off label)



- xx years old patient
- De novo AF ablation for persistent AF (9 months)
- Mapping and ablation with Affera Prism-1/ Sphere-9
- Dispersion analysis with Volta AF-Xplorer



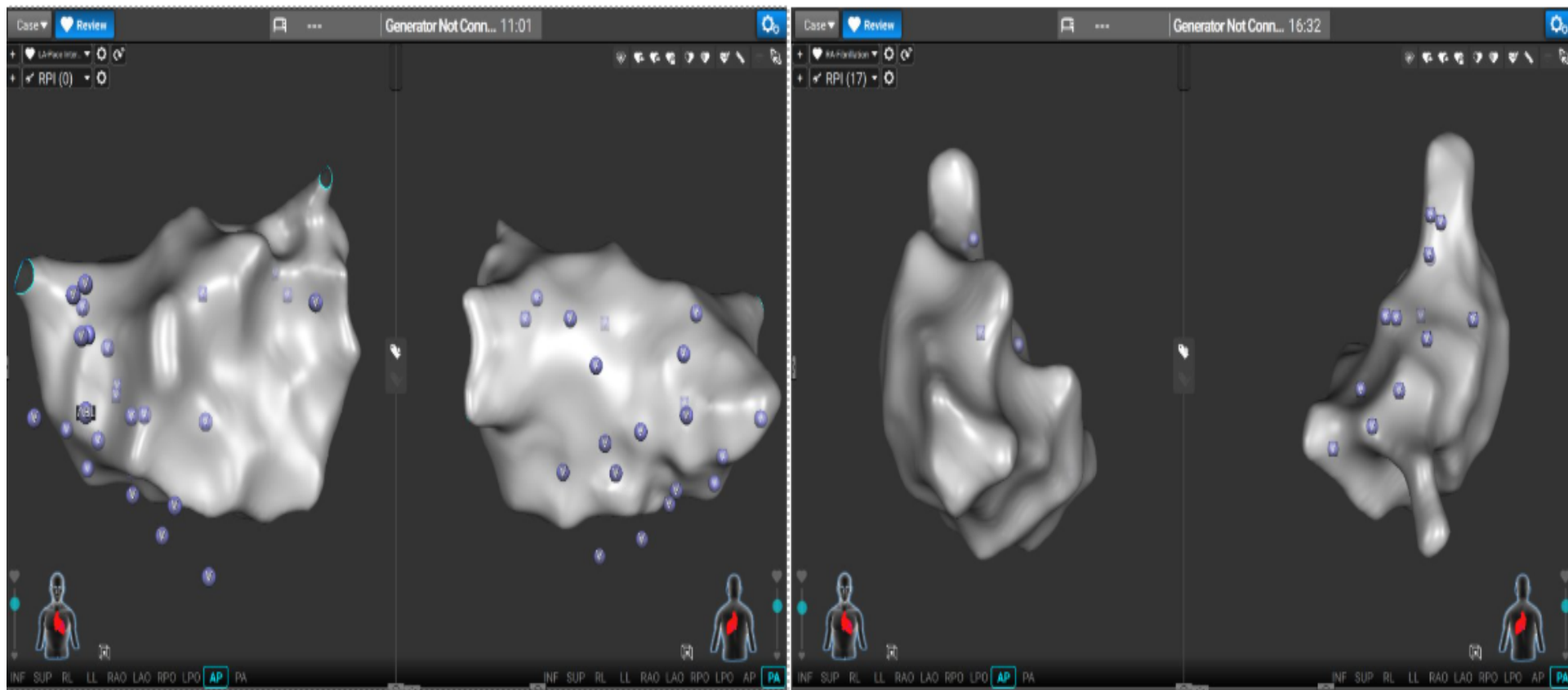
# Persistent AF Case Presentation



- Biatrial mapping with Shere-9 catheter combined with dispersion analysis with Volta AF-Xplorer (off label)

Duration mapping LA : 12min

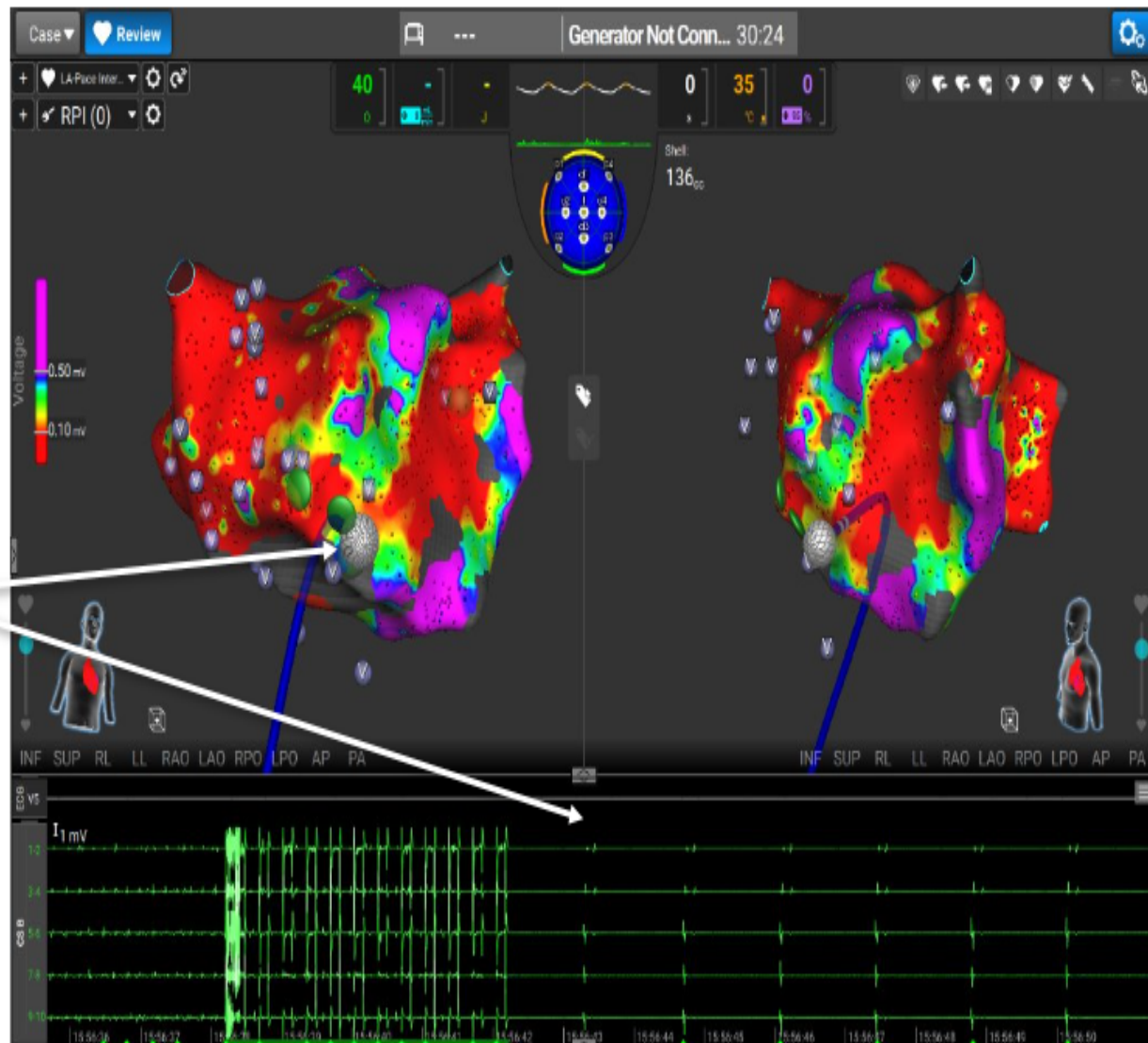
Duration mapping RA : 8min





# AF Termination

Sinus return after  
ablation of an  
identified dispersion  
zone



# Conclusion

- L'électroporation nous offre des perspectives thérapeutiques innovante en terme de sécurité ,efficacité pour le traitement de la fibrillation auriculaire persistante
- La combinaison avec des systèmes de cartographie devrait permettre d'augmenter le nombre de patients éligibles

**H** eart failure

**E** xercise

**A** rterial hypertension

**D** iabetes type 2

**T** obacco

**O** besity

**E** thanol

**S** leep apnoea

## Optimization of AF risk factors

Optimize heart failure medications

≥ 210 min/week of moderate/vigorous exercise

< 130/80 mmHg (rest)  
< 200/100 mmHg (exercise)

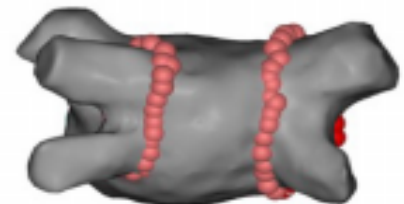
Dietary changes | HbA1c < 7.0%

Complete cessation

≥ 10% weight reduction | BMI < 27 Kg/m<sup>2</sup>

≤ 3 standard drinks/week  
(secondary AF prevention)

AHI < 15 without CPAP |  
CPAP for AHI ≥ 30 or AHI ≥ 20 with HTN



- Consultant: Medtronic, Abbott, Volta