

Atrial Arrhythmias: Novel Technologies:

Novel Lattice Electrode Mapping and Ablation System

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Disclosures

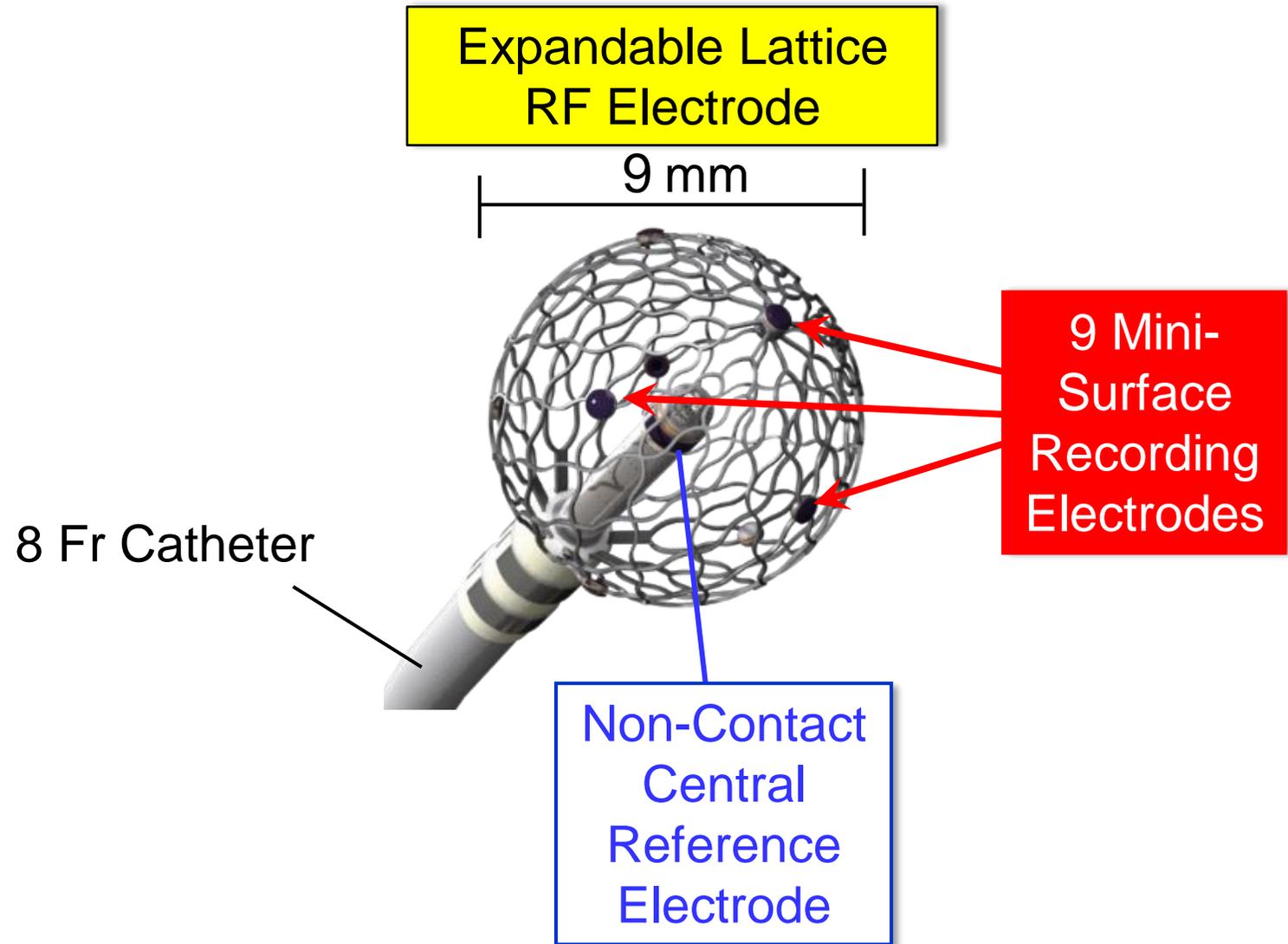
- Research grant and/or consultant for
Affera, Inc., Biosense Webster, Inc., Galaxy Medical, Inc,
Stereotaxis, Inc., Japan Lifeline, Ltd, and Fukuda Denshi, Ltd

BACKGROUND

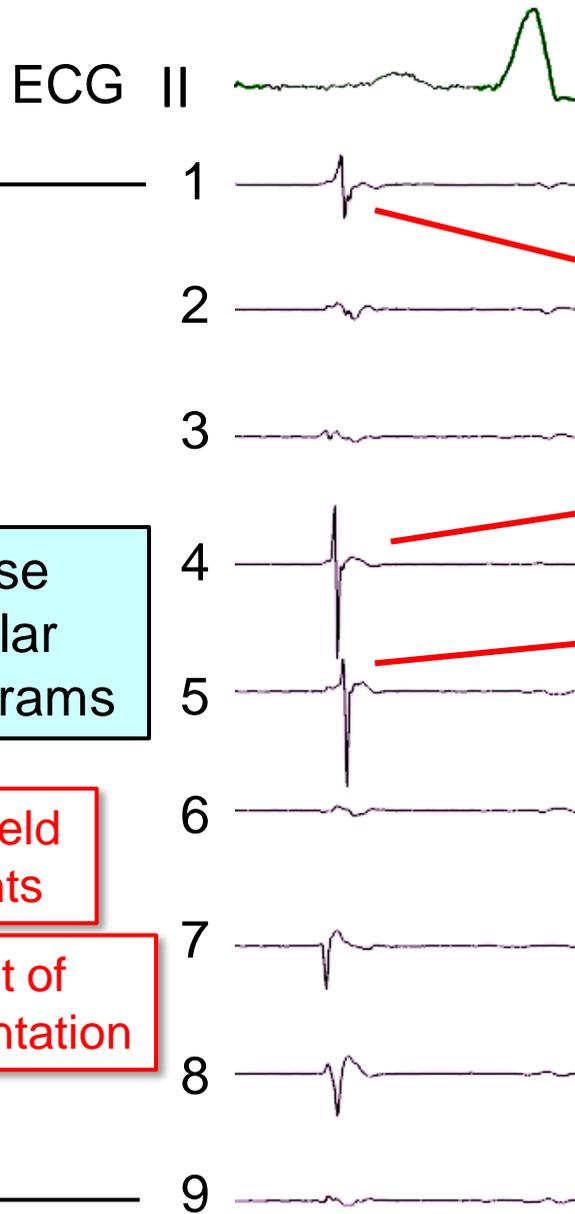
- Using conventional electroanatomical mapping systems,
 - **Unipolar electrograms** between a mapping electrode and a reference electrode (a surface electrode, Wilsons central terminal or an independent electrode located in the IVC)
 - Large far-field components, which often obscure a small local potential
 - **Bipolar electrograms** provide more localized information, but the accuracy of timing depends on **the distance between the two electrodes and the direction of propagation of the wavefront in relation to the orientation of the two electrodes**

“ **Close Unipolar Electrogram** ”

Novel Mapping/ Ablation System (Sphere 9, Affera, Inc)

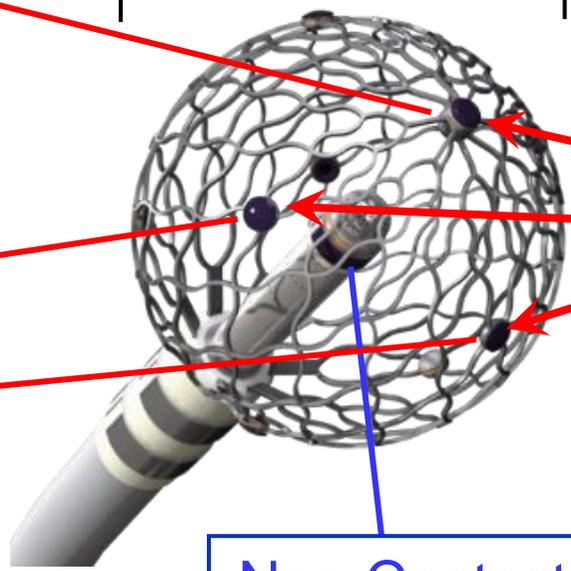


Novel Mapping/ Ablation System (Sphere 9, Affera, Inc)



Expandable Lattice
RF Electrode

9 mm



9 Mini-Surface
Recording
Electrodes

Non-Contact
Central
Reference
Electrode

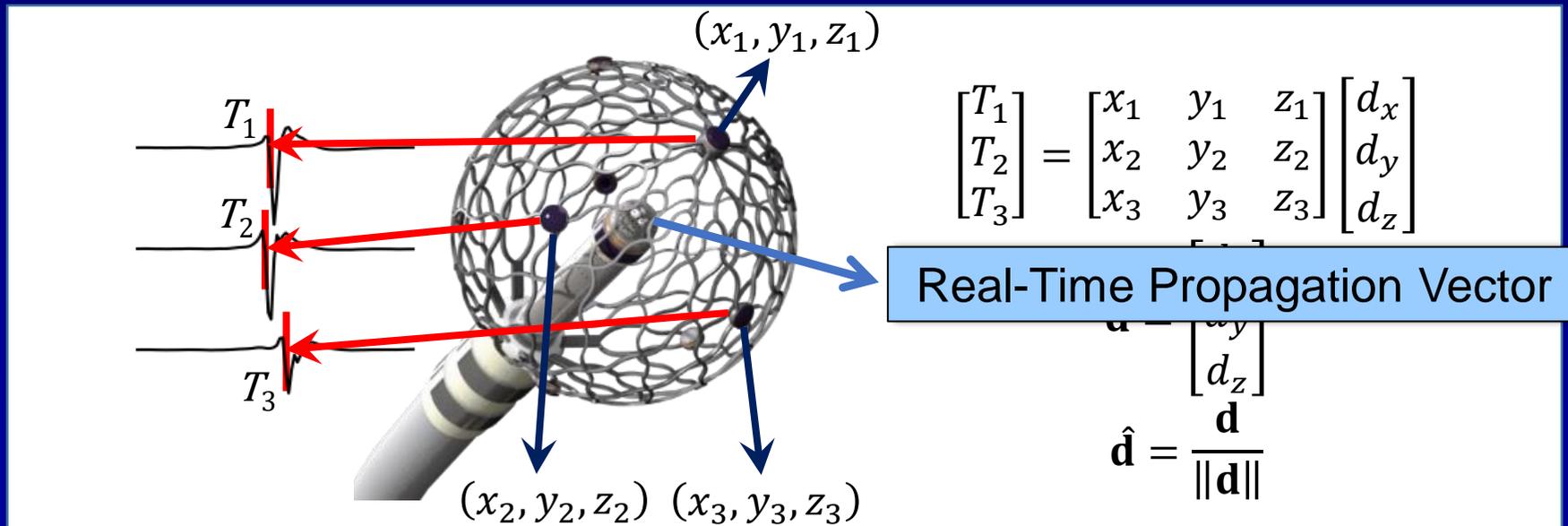
9 Close
Unipolar
Electrograms

Less Far-Field
Components

Independent of
Electrode Orientation

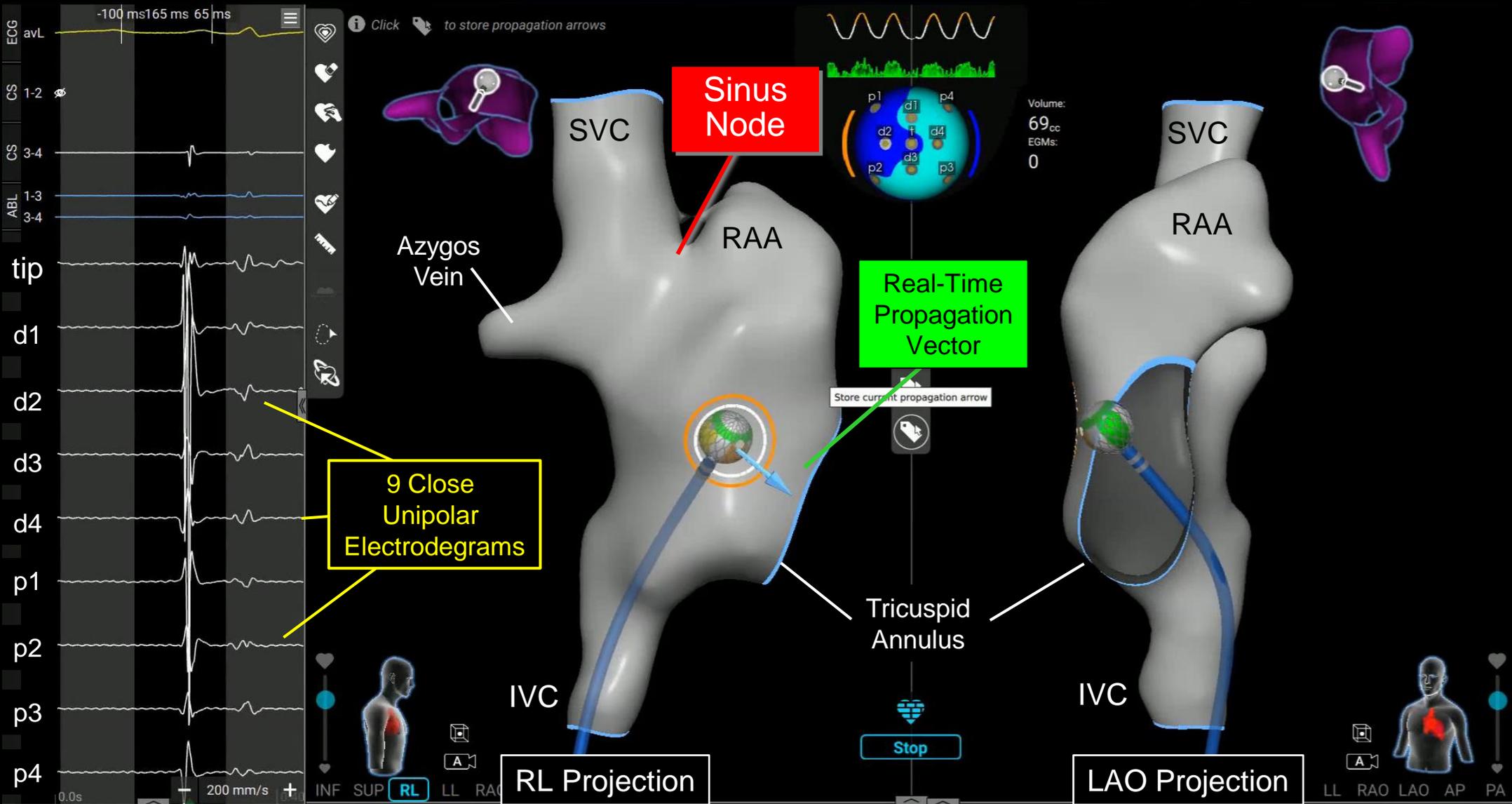
Vector Computation

- Local activation time is annotated based on maximum negative dV/dt of each of 9 CUE (filtered 1-300 Hz)
- **Select 3 adjacent CUE with greatest negative dV/dt** , subject to a minimum threshold
- **Use selected activation times ($T_1, T_2, T_3...$) and locations ($x_1, x_2, x_3...$) to solve for least-squares propagation direction $\hat{\mathbf{d}}$**



Canine RA

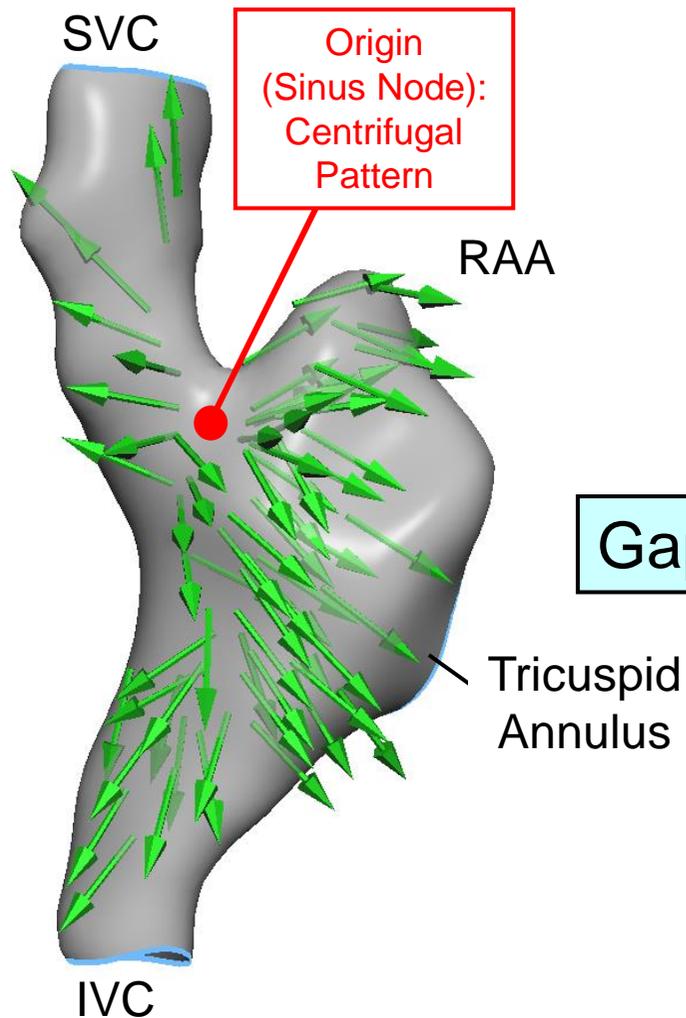
Real-Time Propagation Vector Map



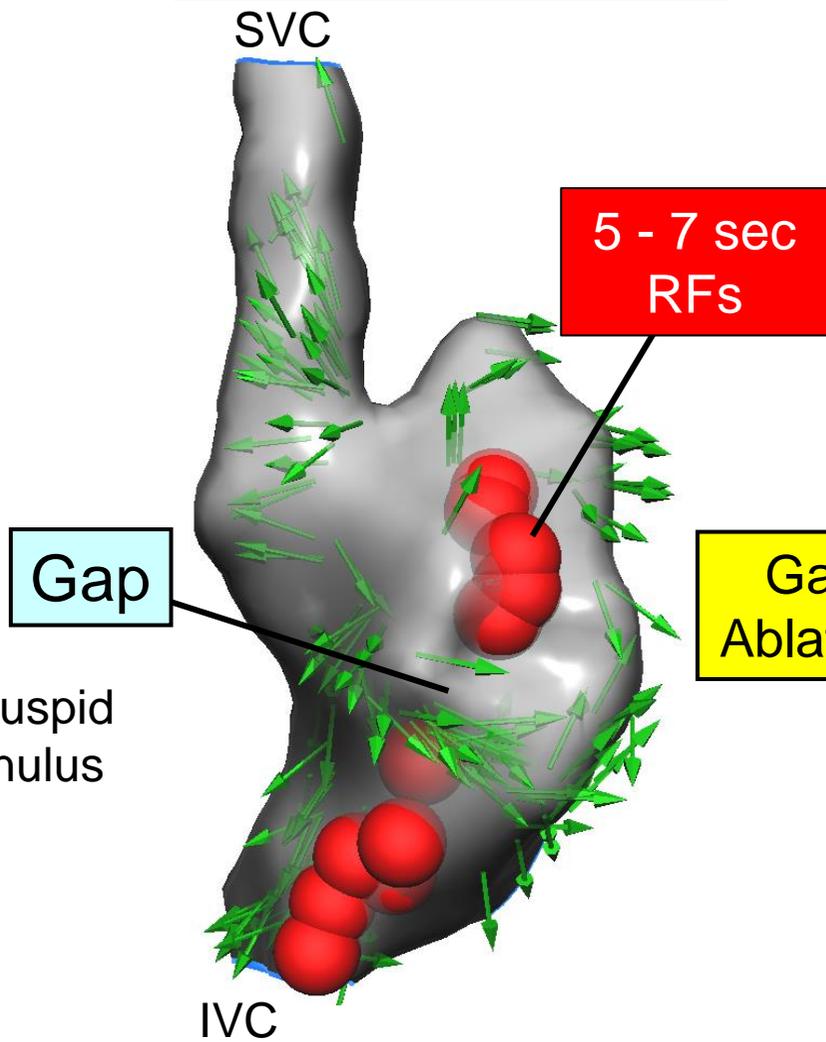
Canine Model

Propagation Vector Map

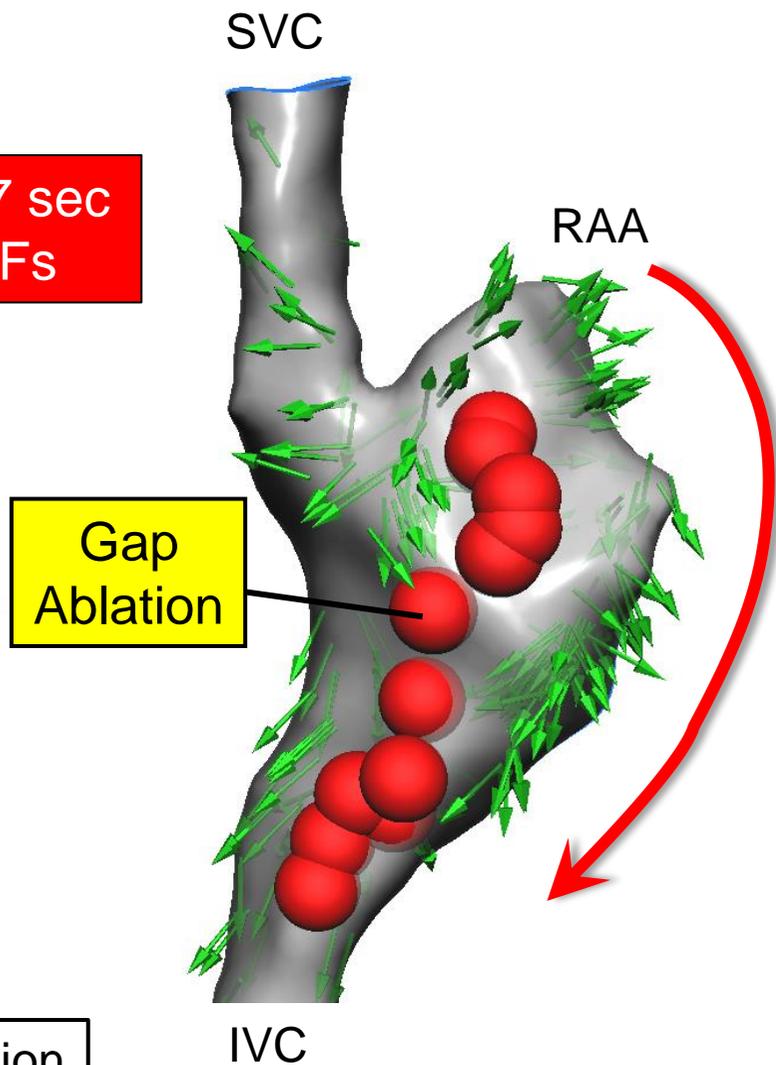
A. Baseline RA Map
(Sinus Rhythm)



B. Post RA Linear Ablation
With a Gap



C. Post Gap Ablation
(Complete Block)



Right Lateral Projection

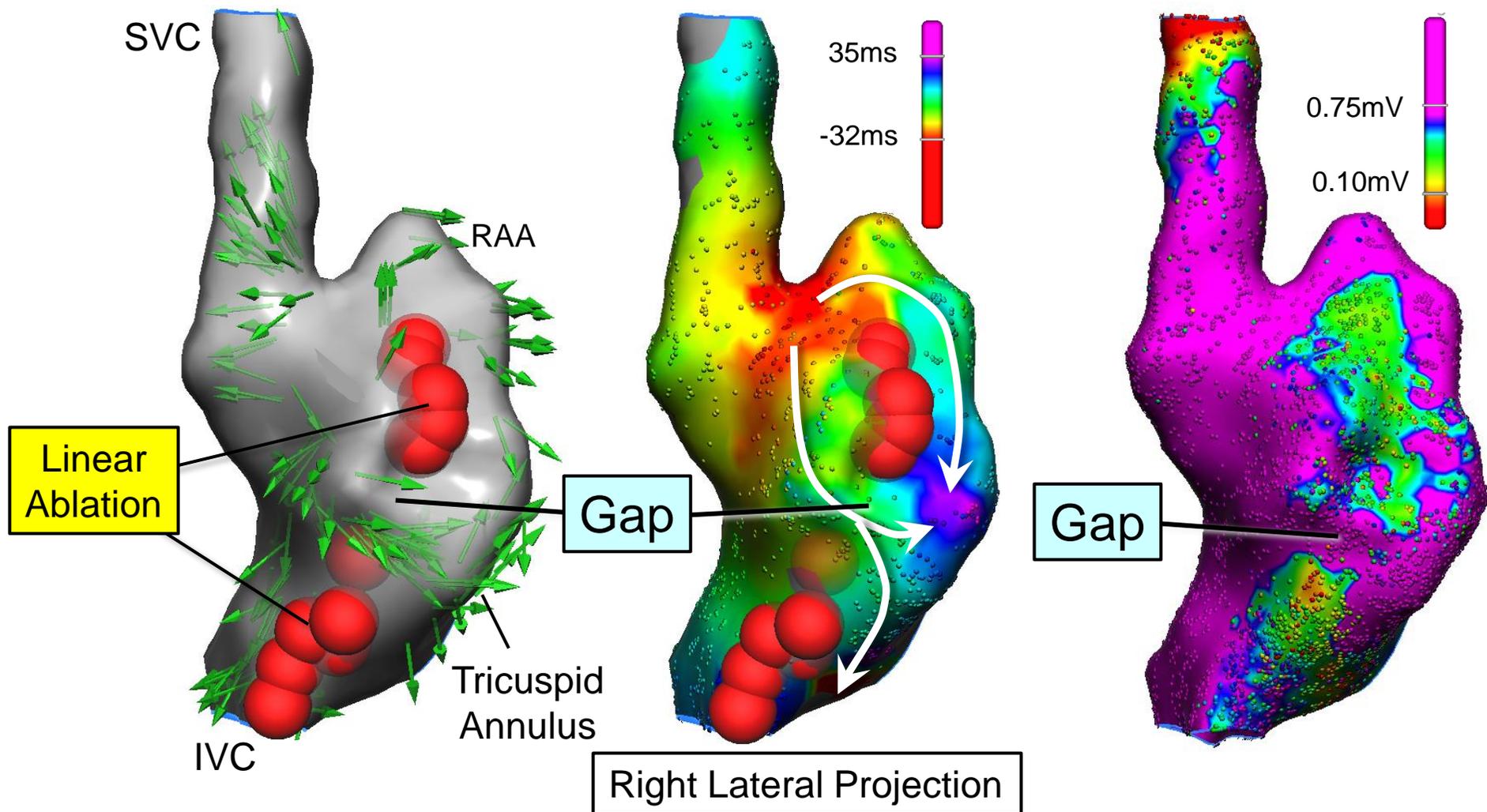
Canine Model

Post RA Linear Ablation With a Gap

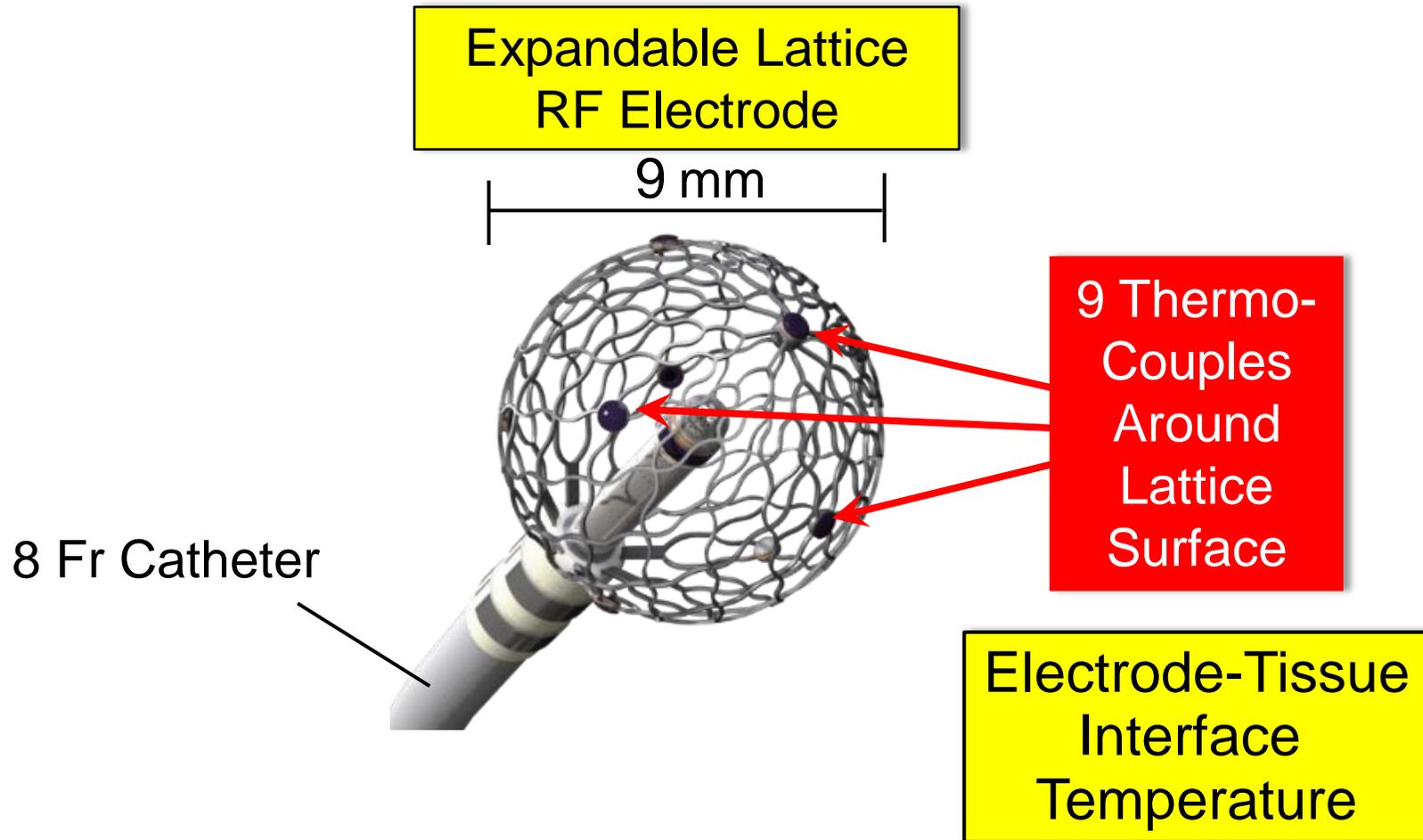
Propagation
Vector Map

Close Unipolar
Activation Map

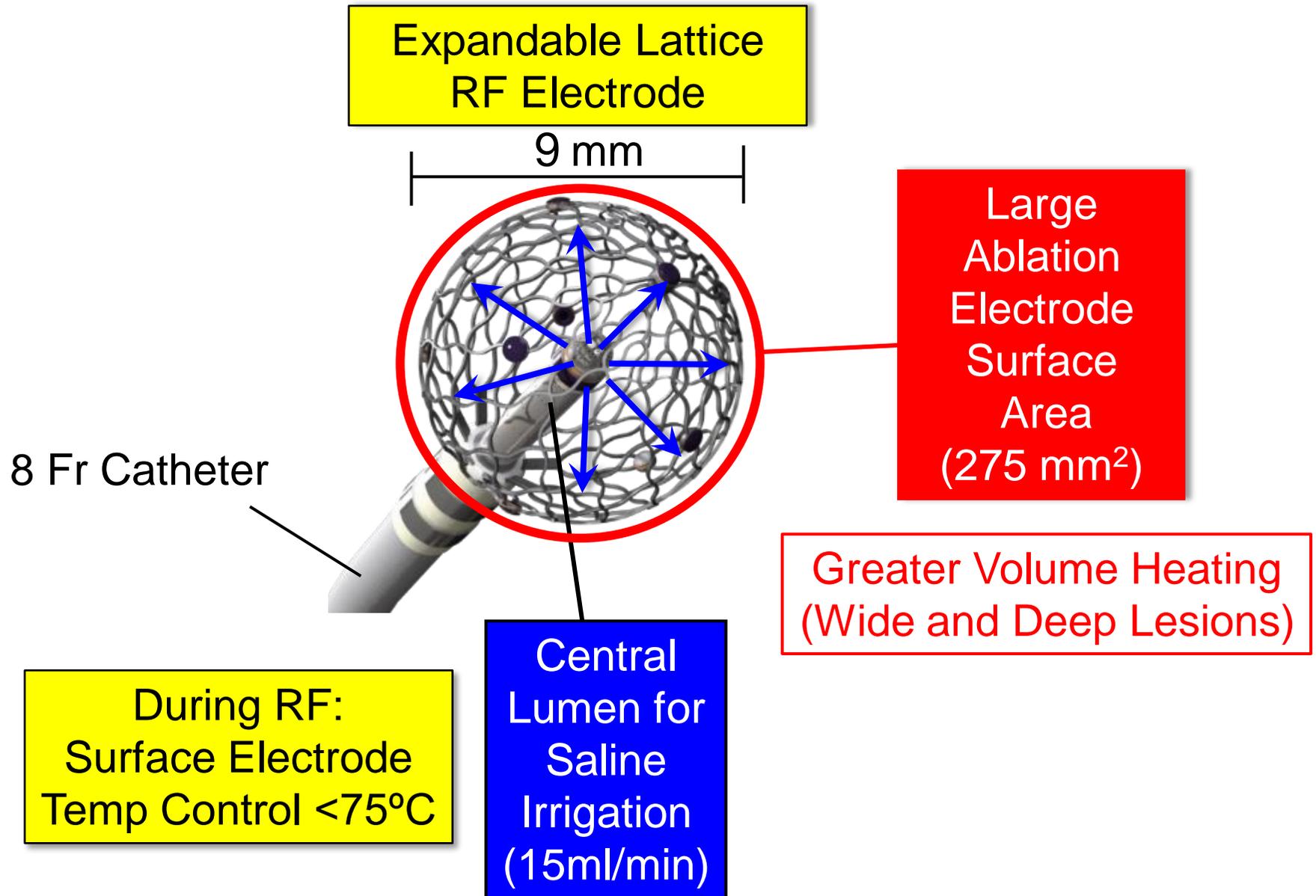
Close Unipolar
Voltage Map



Mapping/ Ablation System (Sphere 9)



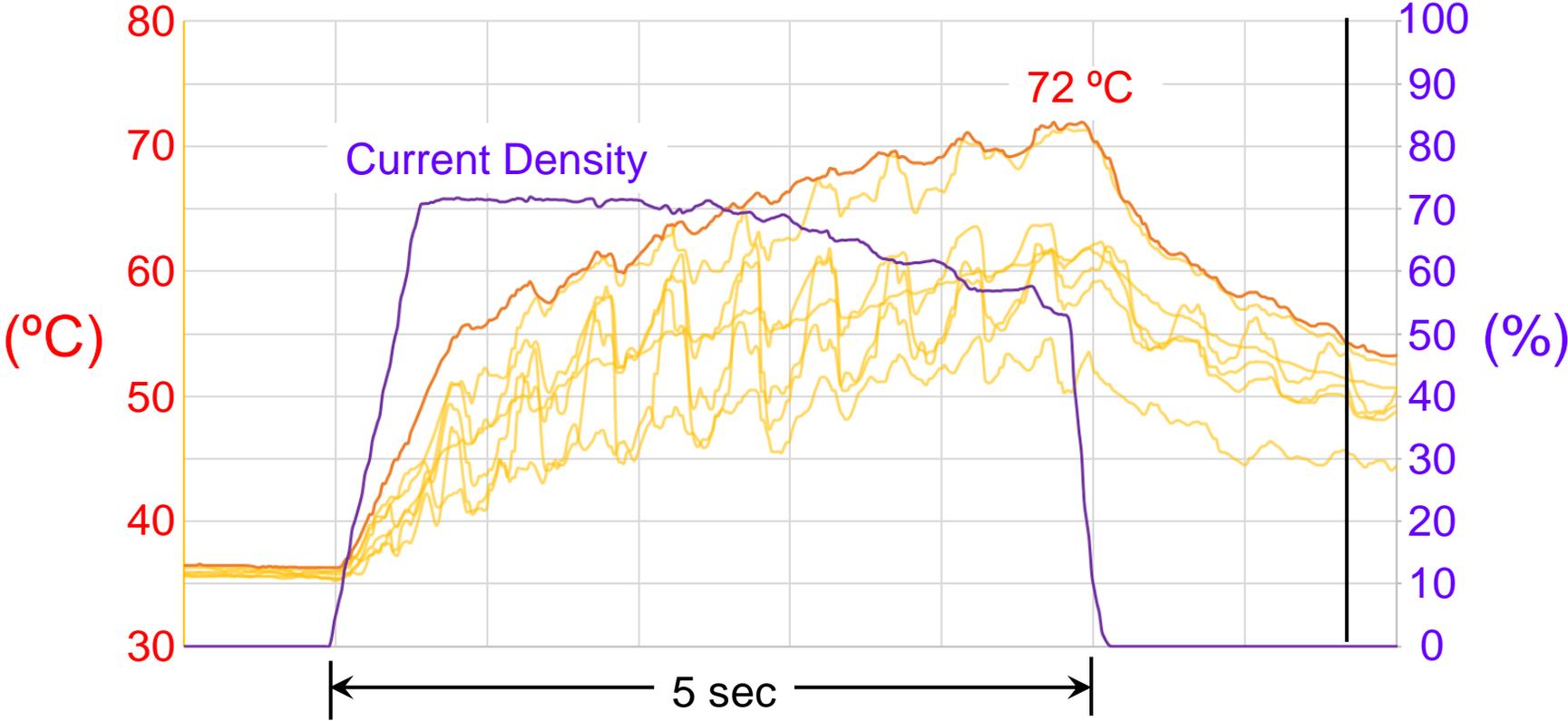
Mapping/ Ablation System (Sphere 9)



Lattice Electrode RF Application
(5 sec, 75°C)

Temp at Surface
Thermocouples

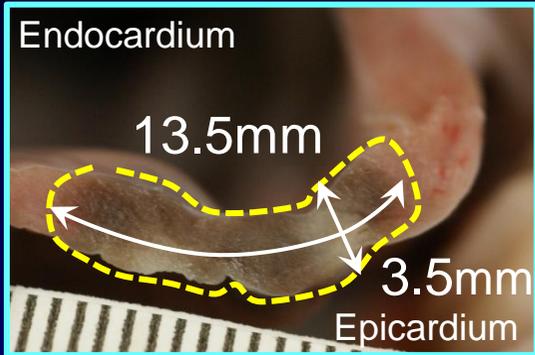
Current Density
(% of 13.5 mA/mm²)



Average Current Density <10 mA/mm²
(7Fr - 4mm Electrode: <25Watts)

Atrial and Ventricular Ablation in a Canine Model

Transmural LA Lesion (5 sec RF, 75°C)



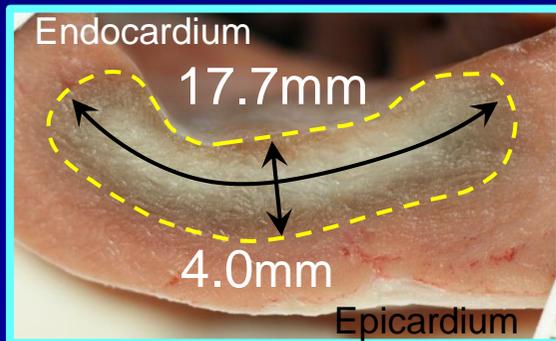
Wide transmural lesions in the RA and LA

- 5 sec RF applications:

15/17 (88%) lesions were transmural

maximum diameter - median **14.2 mm**
depth - median **3.0 mm**

Non-Transmural RV Lesion (7 sec RF)



Cross-Sectional View

Wide and shallow lesions in the RV

- 5 sec RF applications:

maximum diameter - median **11.8 mm**
depth - median **3.7 mm**

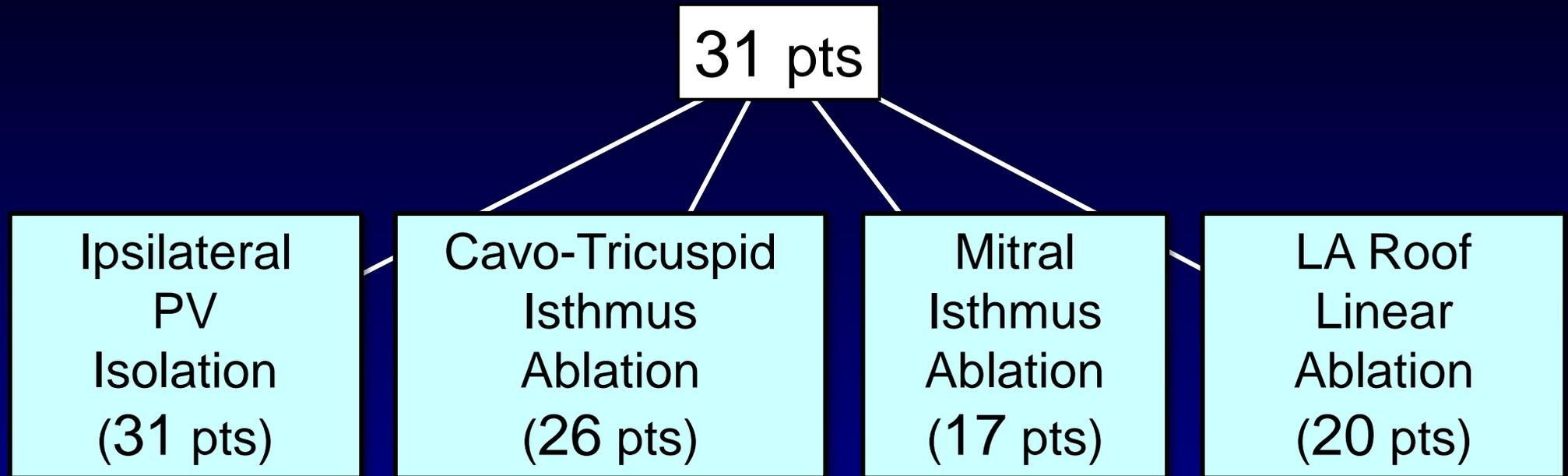
- 7 sec RF applications:

maximum diameter - median **14.2 mm**
depth - median **4.4 mm**

Clinical Study (First-in-Man Trial)

- Test feasibility of the system for rapid linear RF ablation for ipsilateral pulmonary vein (PV) isolation and across cavo-tricuspid isthmus (CTI), mitral isthmus (MI) and LA roof line in patients undergoing AF or AFL ablation
- IKEM, Prague, Czech Republic
Josef Kautzner, MD and Petr Peichl, MD

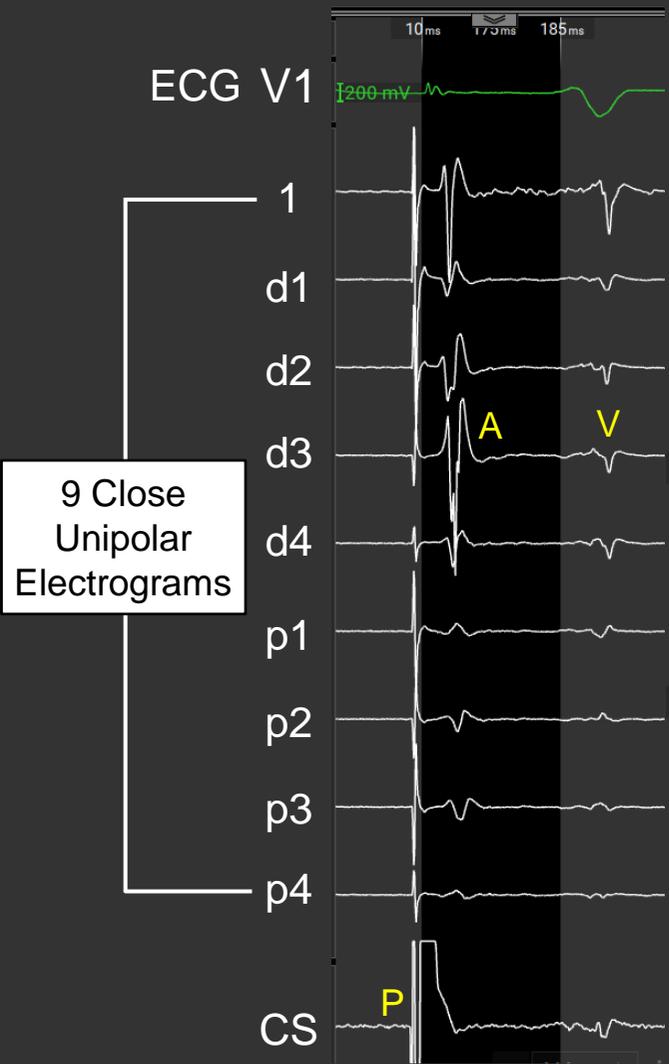
Study Population



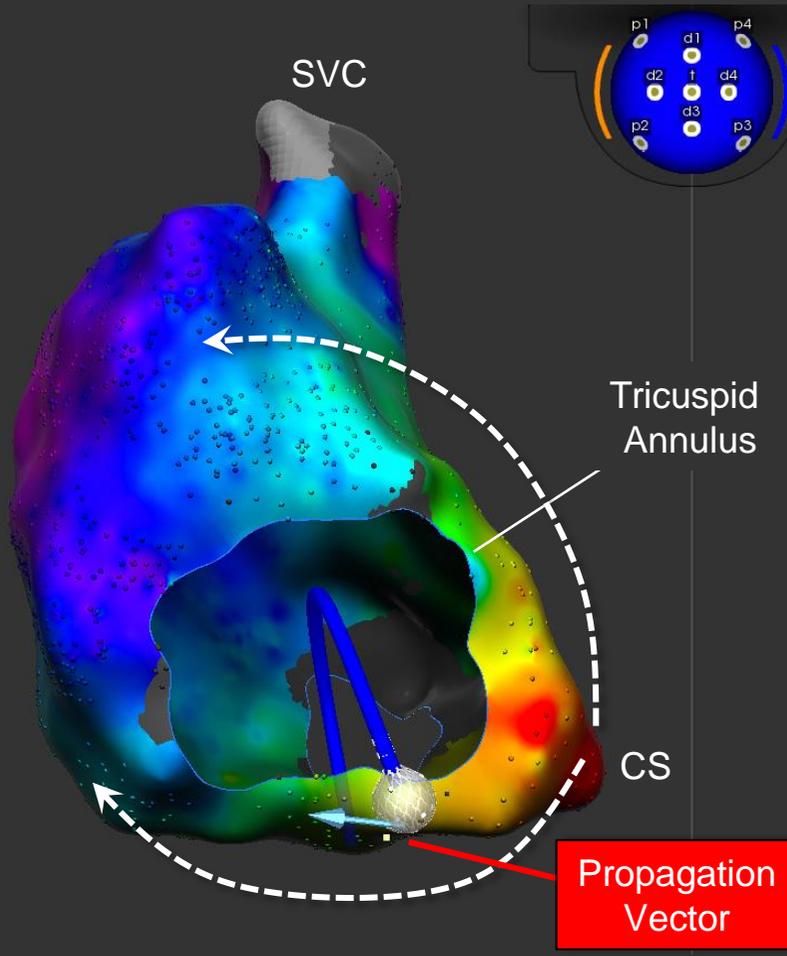
Irrigation: 15 ml/min
Surface Electrode Temp $\leq 75^{\circ}\text{C}$
RF Current Density $\leq 13.5 \text{ mAmp/mm}^2$

RF Time
2.5 sec – 5sec

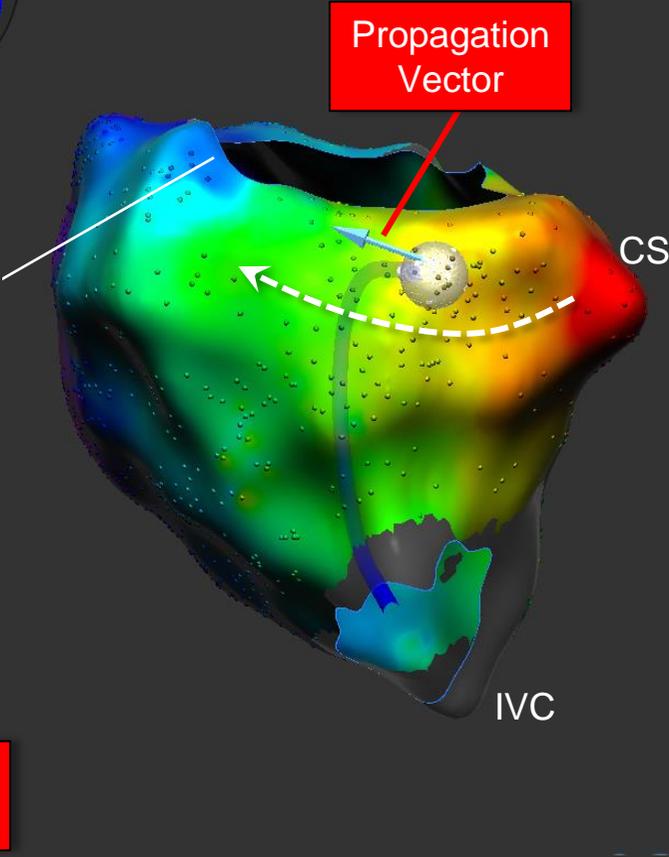
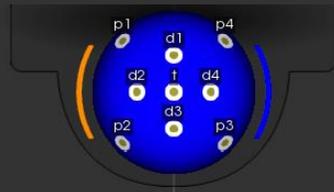
Close Unipolar Activation Map (During CS Pacing)



Right Lateral Projection



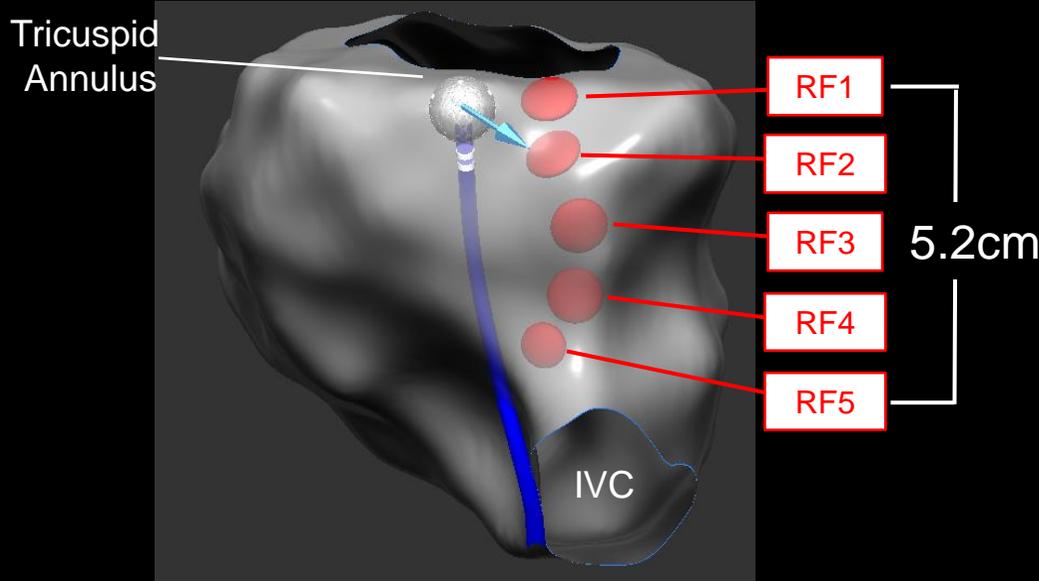
LAO Projection



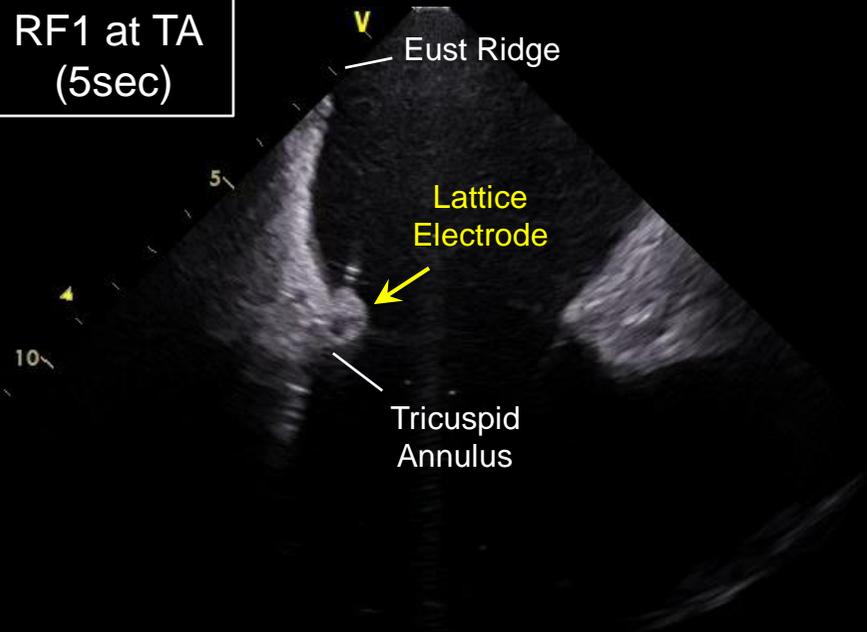
LAO-Caudal Projection

CTI Ablation

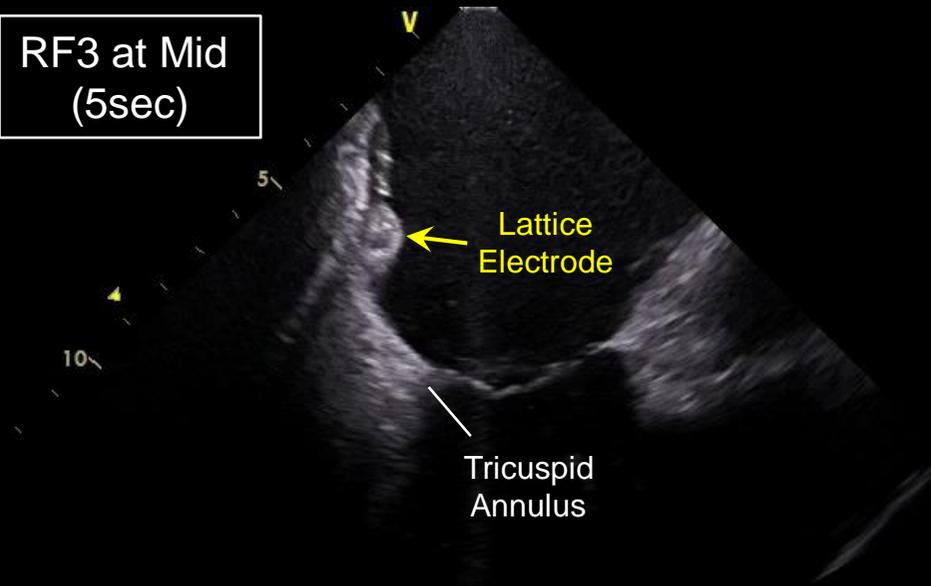
3sec or 5se x 5RFs (Total 23 sec)



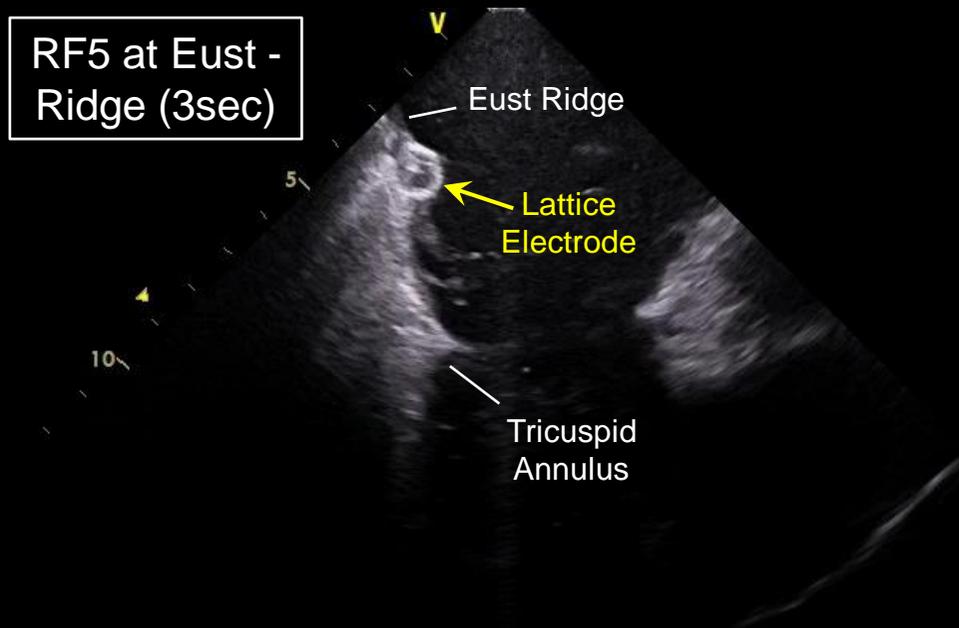
RF1 at TA
(5sec)



RF3 at Mid
(5sec)

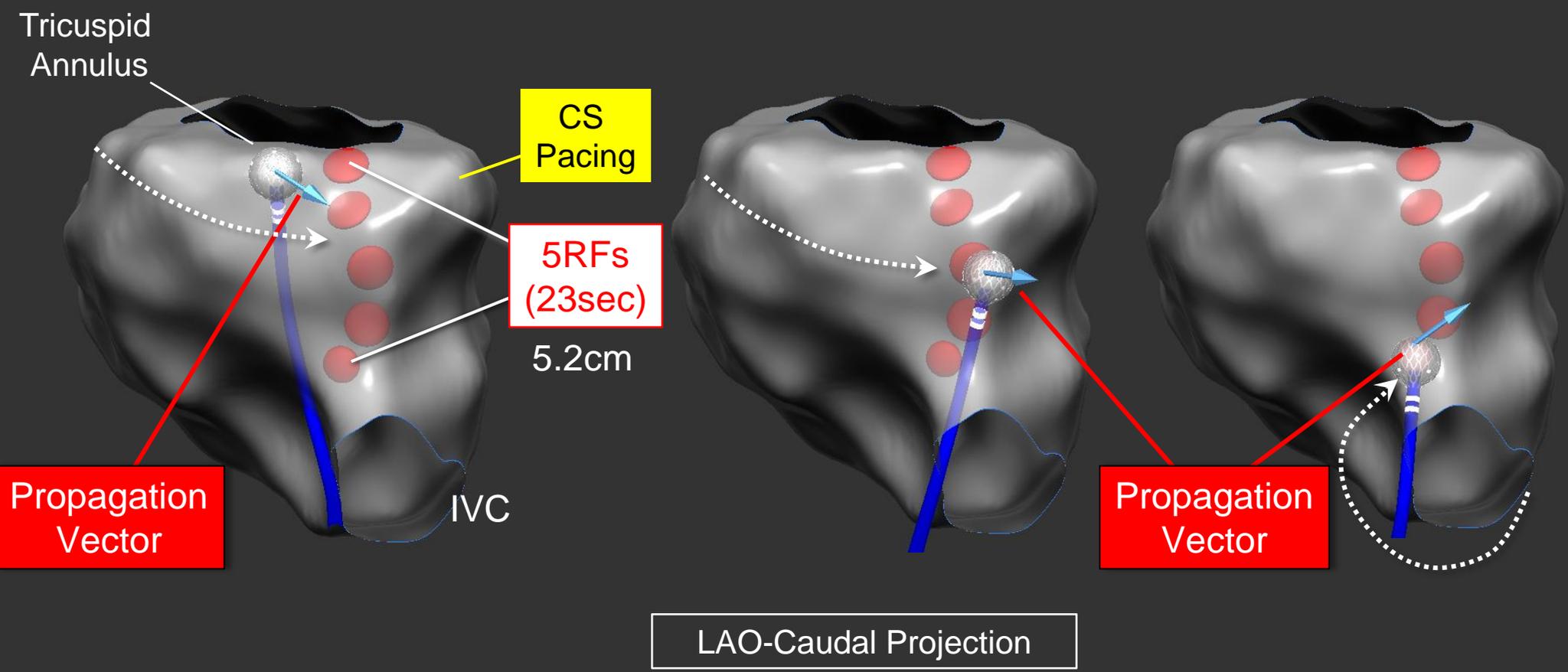


RF5 at Eust -
Ridge (3sec)

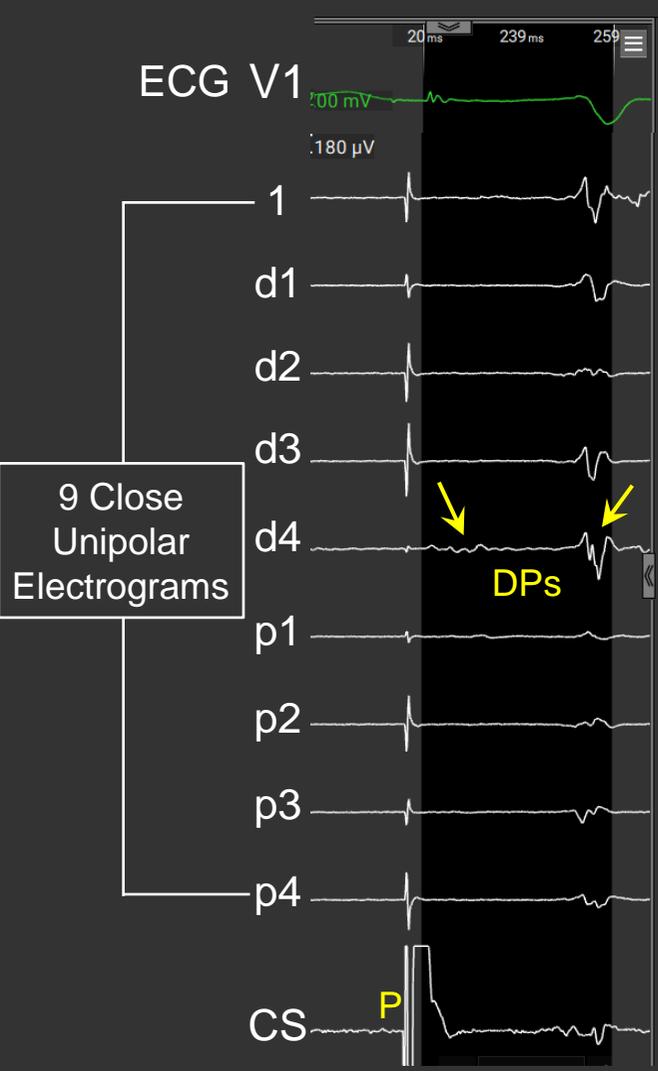


Post-CTI Ablation (During CS Pacing)

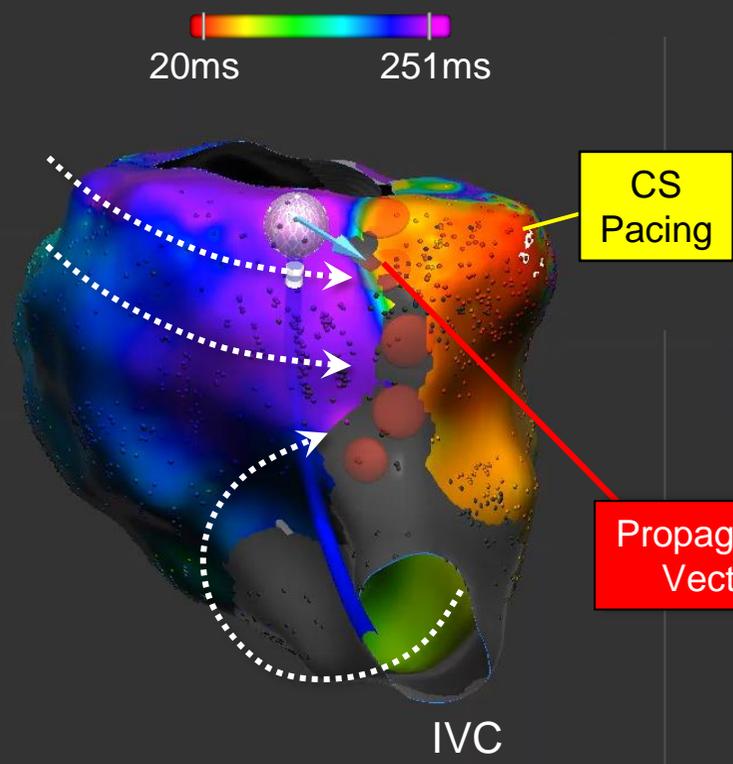
Real-Time Propagation Vector Map



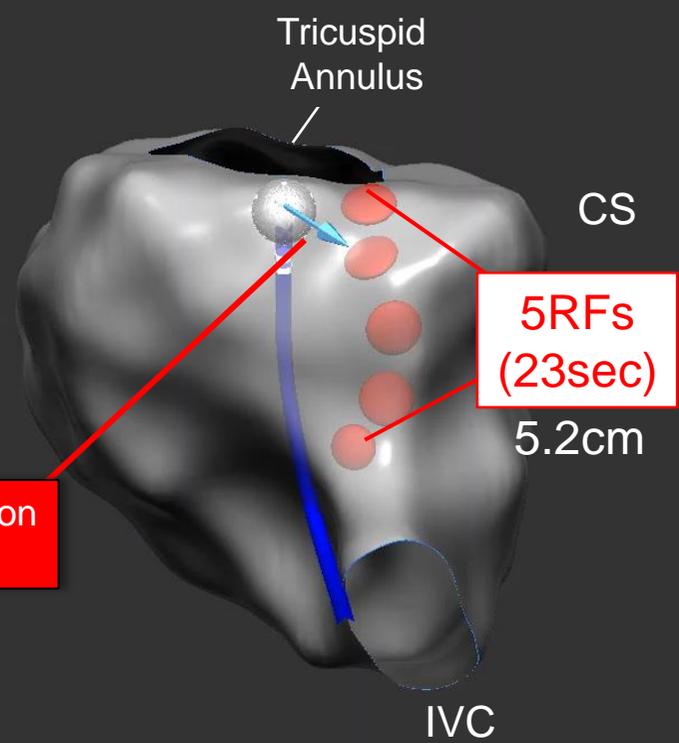
Post-CTI Ablation (During CS Pacing)



High-Density Close Unipolar Activation Map



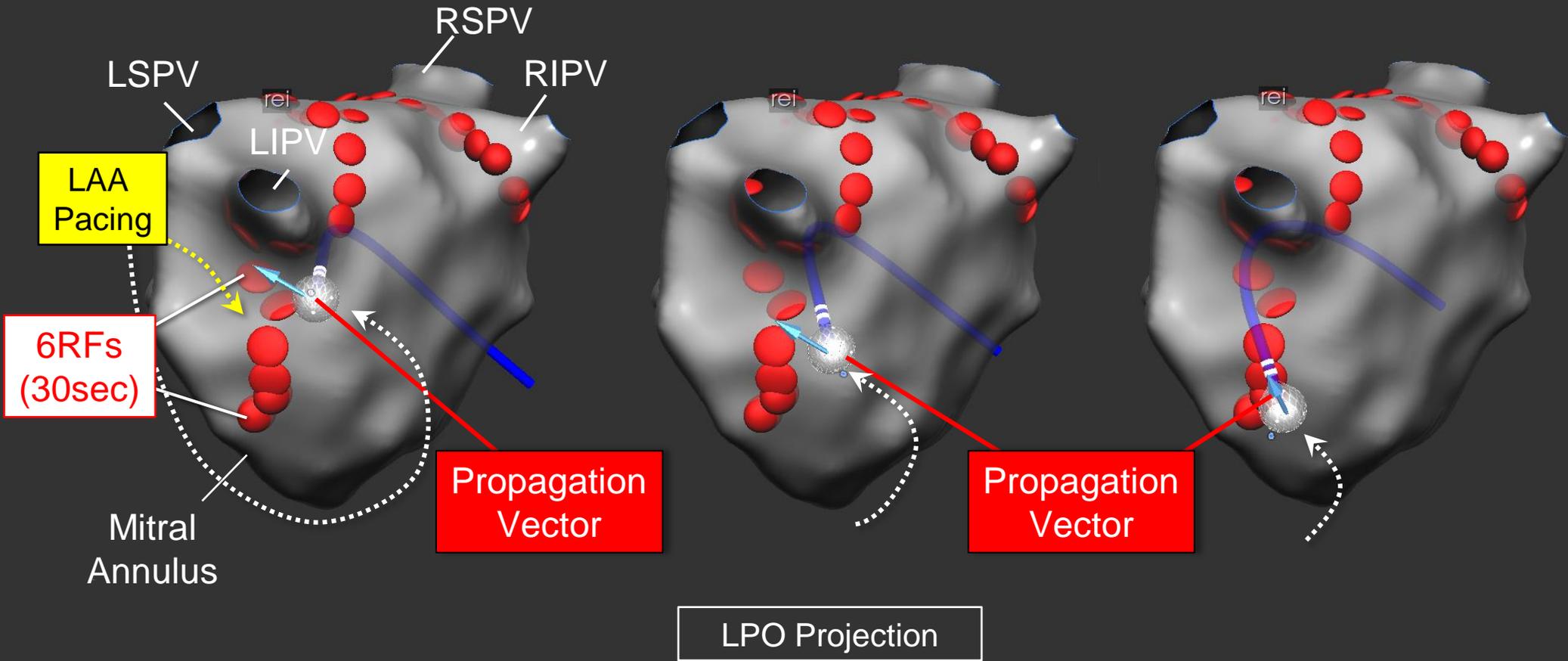
Real-Time Propagation Vector Map



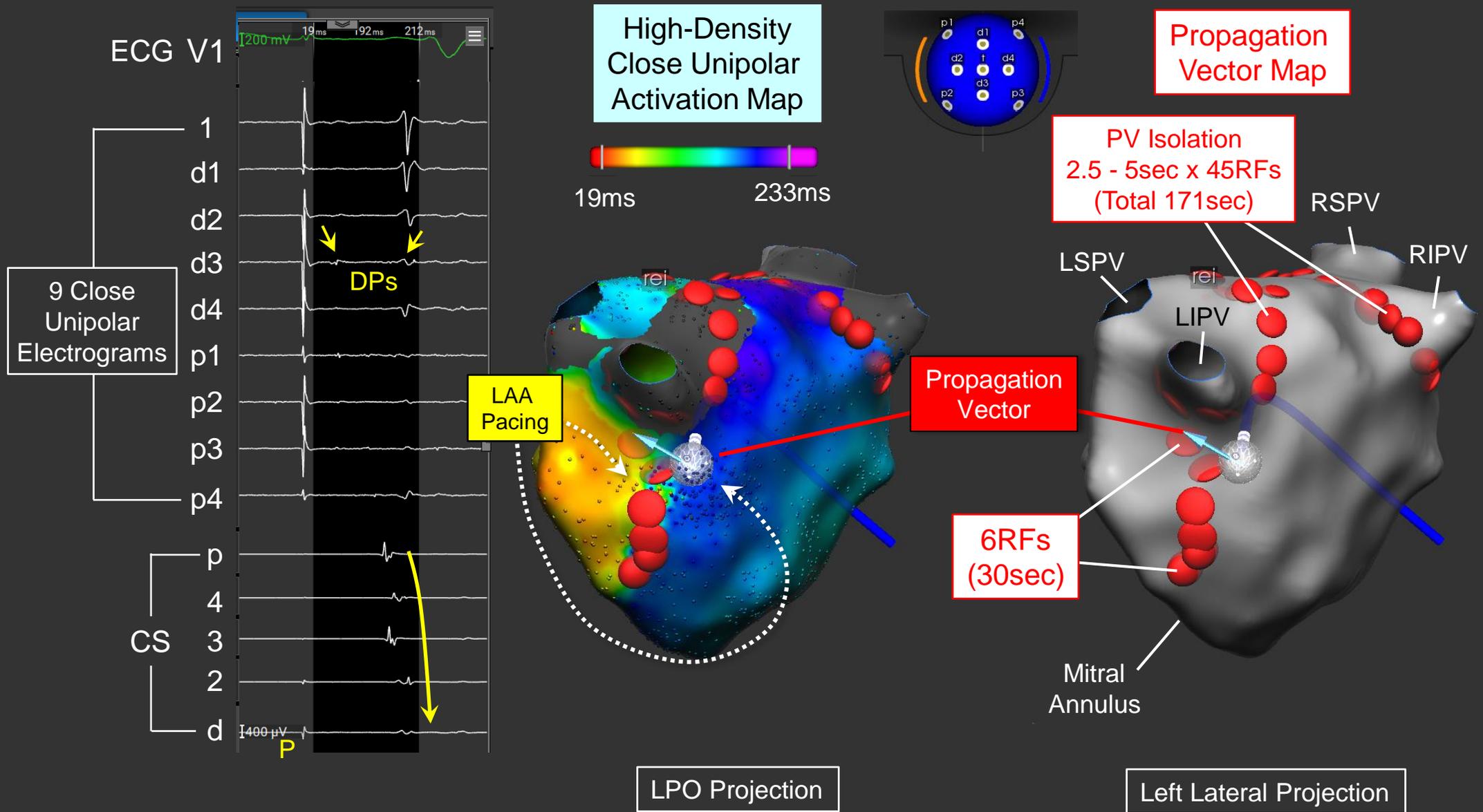
LAO-Caudal Projection

Post-Mitral Isthmus Ablation (During LAA Pacing)

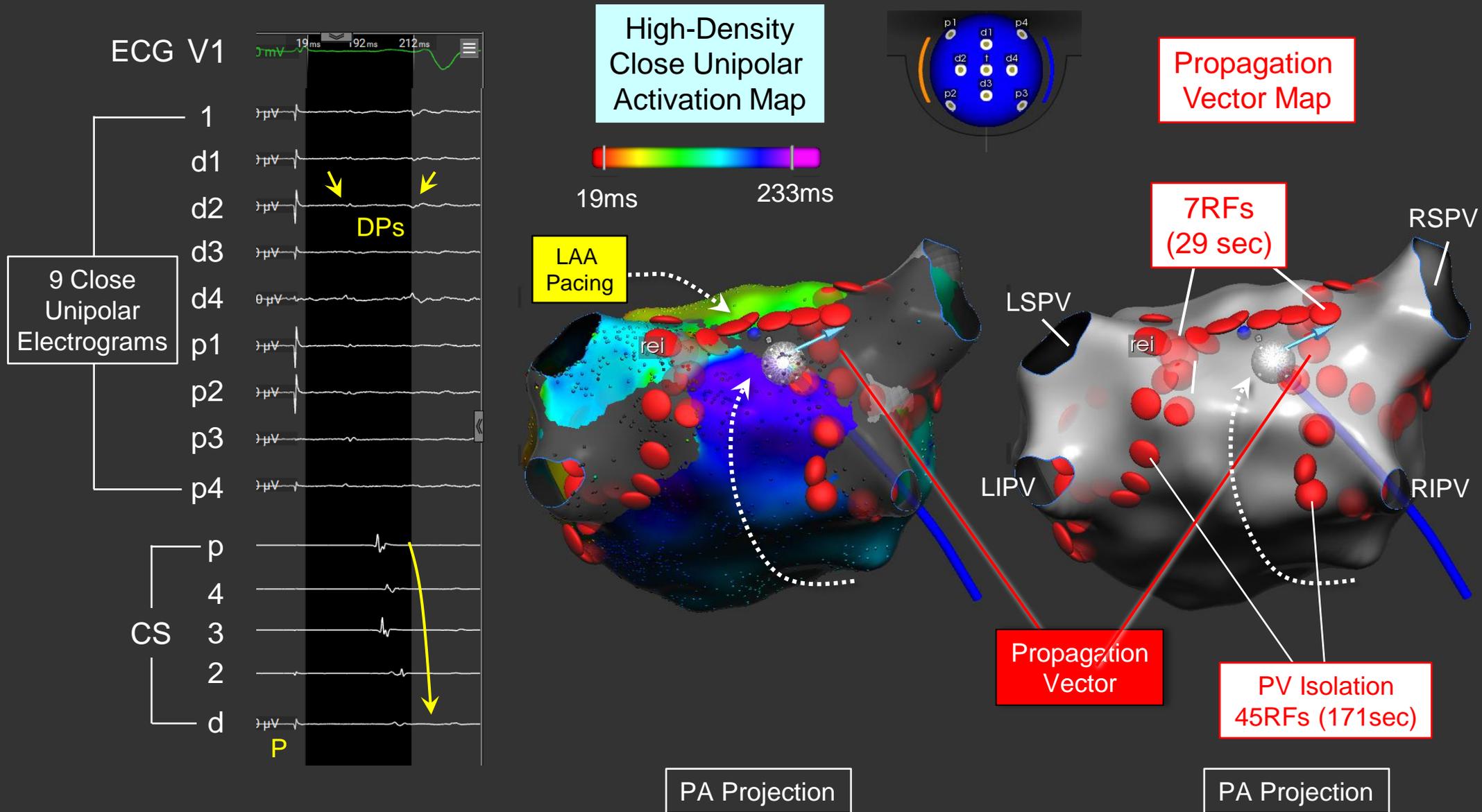
Real-Time Propagation Vector Map



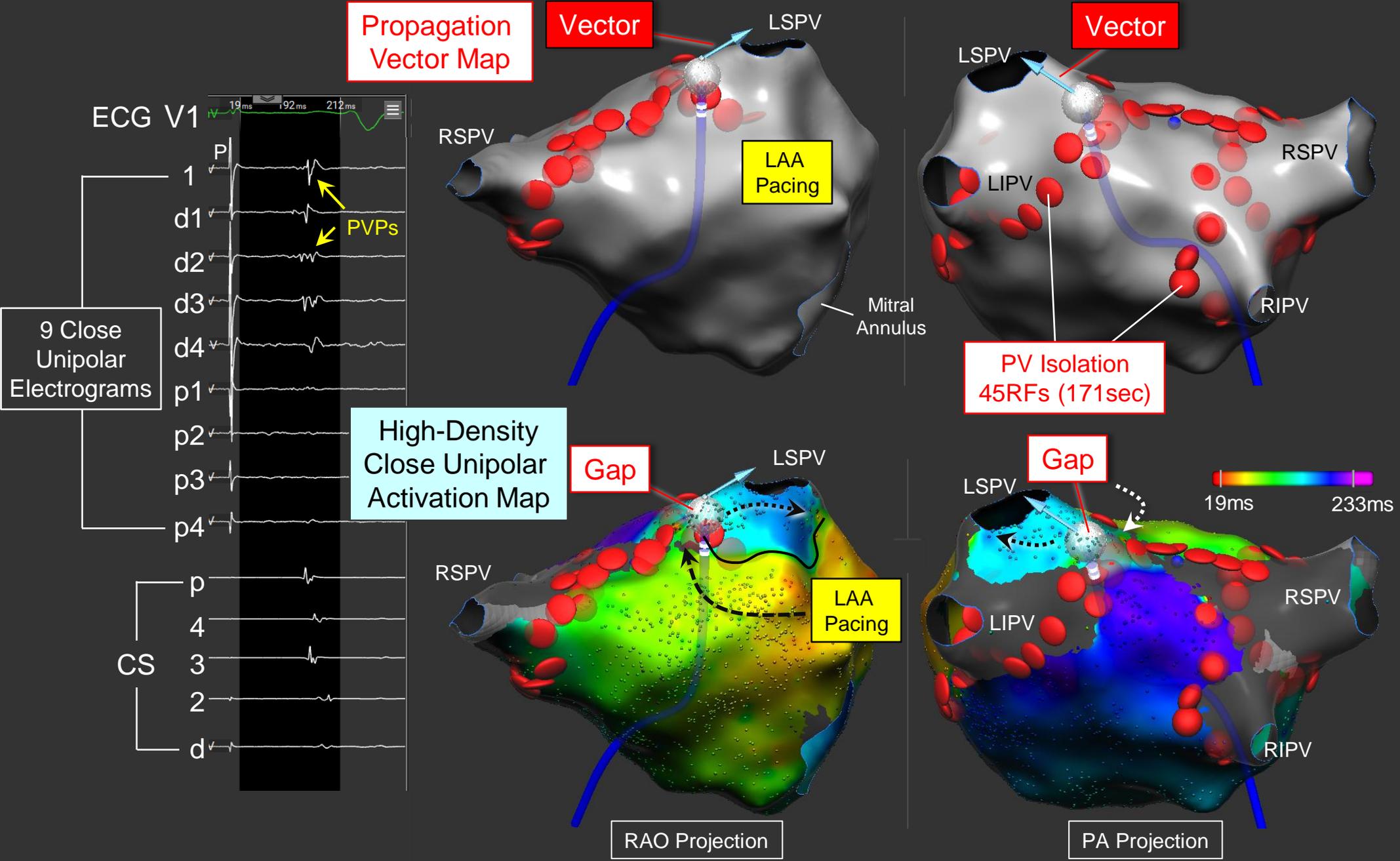
Post-Mitral Isthmus Ablation: 5sec x 6RFs (Total 30sec) (During LAA Pacing)



Post - LA Roof Ablation: 2.5sec - 5sec x 7RFs (Total 29sec) (During LAA Pacing)



Identification of a Gap Along the PV Isolation Line (LAA Pacing)



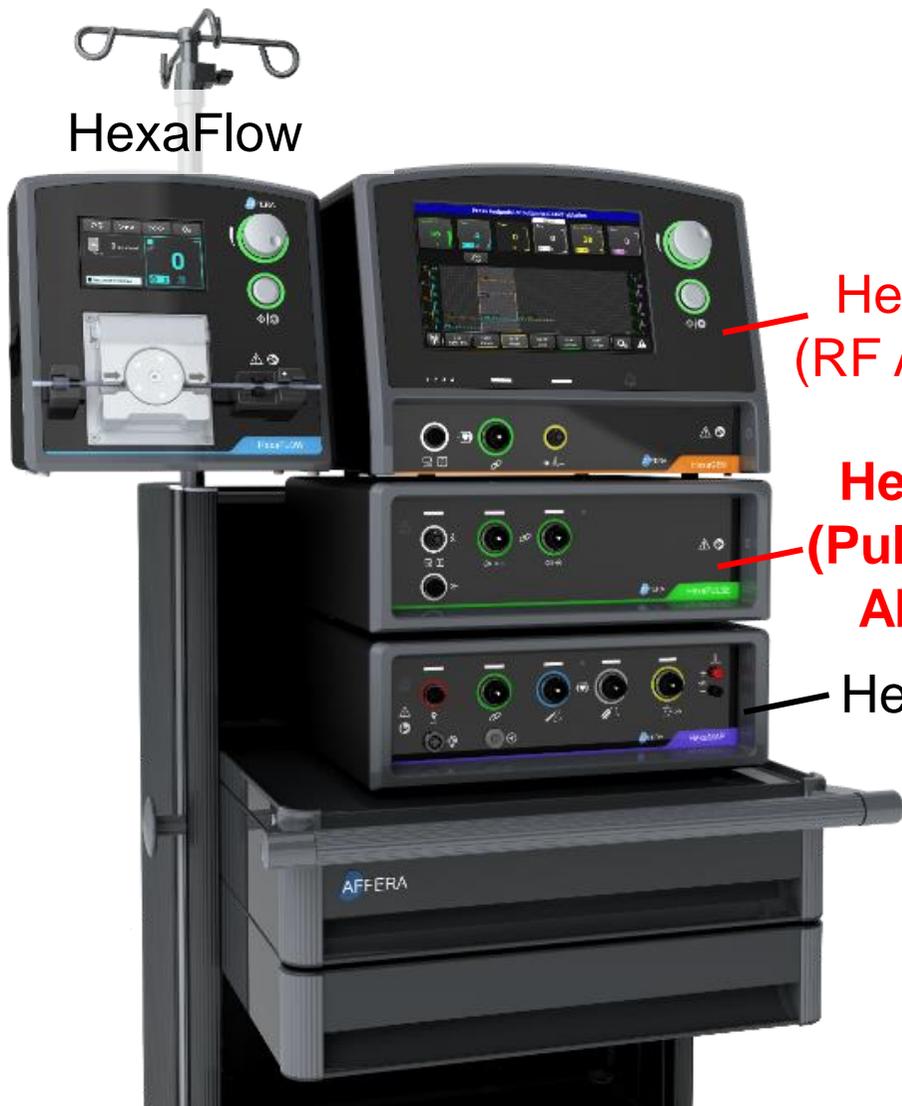
Lattice Electrode RF Ablation Results

- Complete conduction block was obtained:
 - Ipsilateral PV Isolation (Right & Left) **31/31 pts**
30 - 61 RFs (median 39)
Total RF Time 103 - 300 sec (median 173 sec)
 - CTI **7/7 pts**
2 - 22 RFs (median 5)
Total RF Time 10 - 106 sec (median 25 sec)
 - Mitral Isthmus **3/3 pts**
3 - 49 RFs (median 6)
Total RF Time 15 - 245 sec (median 35 sec)
 - LA Roof Line **5/6 pts**
2 - 11 RFs (median 6)
Total RF Time 6 - 51 sec (median 26 sec)

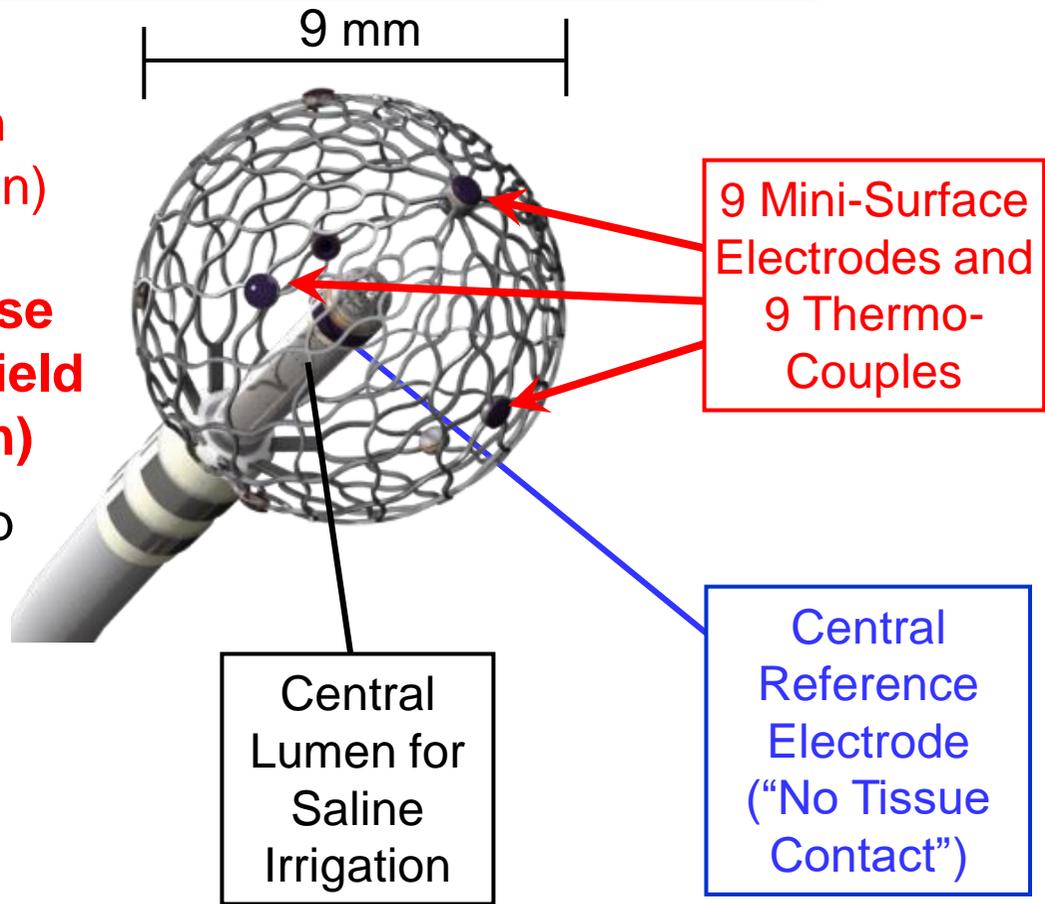
Lattice Electrode Mapping Results

- Real-time propagation vector maps rapidly Identified and accurately localized:
 - Conduction before completing linear lesion 14/14 pts
 - Gap along the linear ablation 2/2 pts
 - Development of complete block 13/13 pts
 - Accuracy of propagation vector maps was confirmed by high-density CUE activation maps 14/14 pts

RF/PF Ablation System (HexaGen and HxaPulse, Affera, Inc)



8 Fr Deflectable Catheter,
Expandable Lattice Tip Electrode Catheter
(Sphere-9, Affera, Inc)



HexaGen
(RF Ablation)

HexaPulse
(Pulsed Field
Ablation)

HexaMap

9 Mini-Surface
Electrodes and
9 Thermo-
Couples

Central
Reference
Electrode
("No Tissue
Contact")

Central
Lumen for
Saline
Irrigation

RF/PF Ablation Protocols

RF Ablation:

- RF Current Limit: 85% - 100% of 13.6 mA/mm²
- Surface Electrode Temperature Control: 73-75°C
- RF Time: 3 – 7 sec
- Saline Irrigation: 15ml/min

Pulsed Field (PF) Ablation:

- PF Current: 24 – 32 Amps
- Biphasic microsecond-scale pulses
- Delivered over 3-5 sec (Synchronized to either atrial or ventricular depolarization)
- Saline Irrigation: 15 ml/min

Prospective, Multicenter, Single Arm Study

IKEM and Homolka Hospital, Prague
Vilnius University, Lithuania

76 pts

(Paroxysmal AF 55pts, Persistent AF 21 pts)

RF/ Pulsed Field (PF)
Ablation
(40 pts)

Only Pulsed Field (PF)
Ablation
(36 pts)

Ipsilateral PV Isolation &
Mitral Isthmus Line
LA Roof Line
CTI Line
LA Posterior or Anterior Line

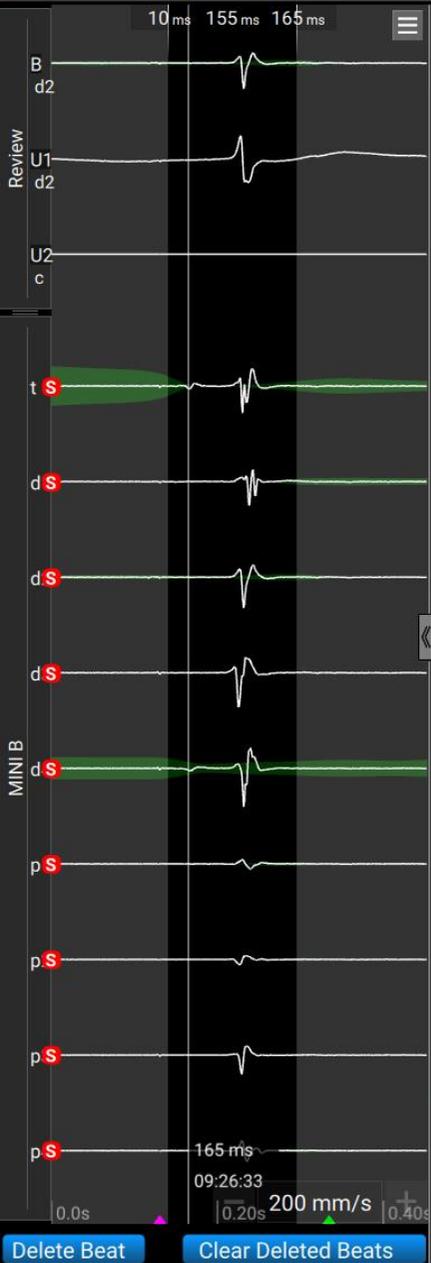
IKEM Case

Ipsilateral PV Isolation with PF Ablation Only

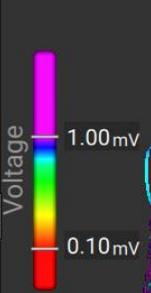
Total PF Time: 2 min 50 sec

Ablation Procedure Time: 15 min

PAF
(68 yrs, Male)

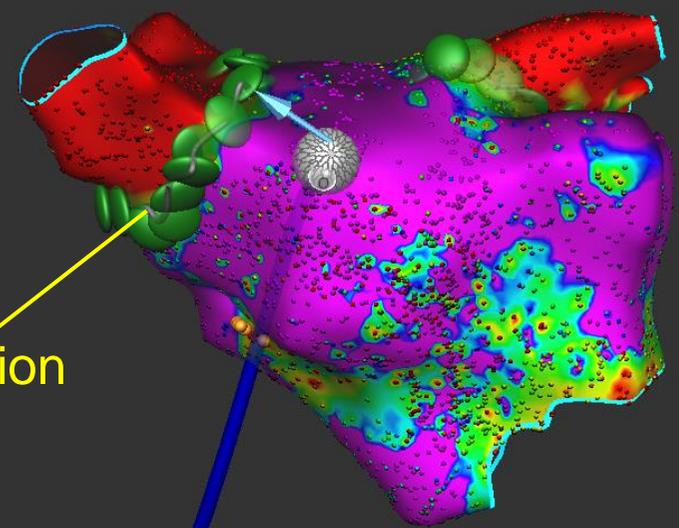


+ None
+ CTI (0)



CS Pacing

PA Projection



RAO Projection



Close Unipolar Voltage Map

PF Ablation

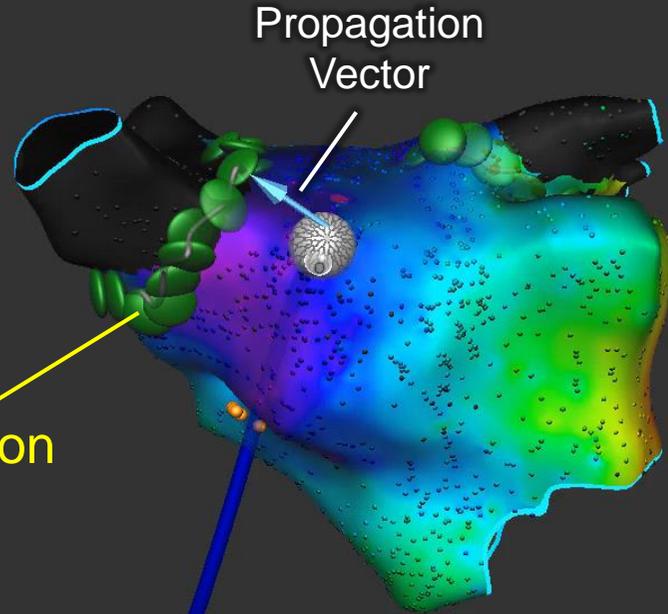
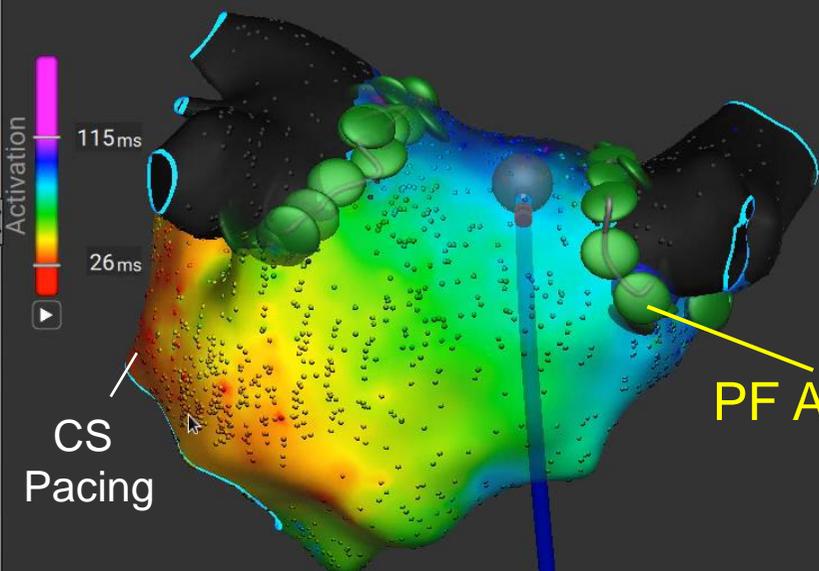
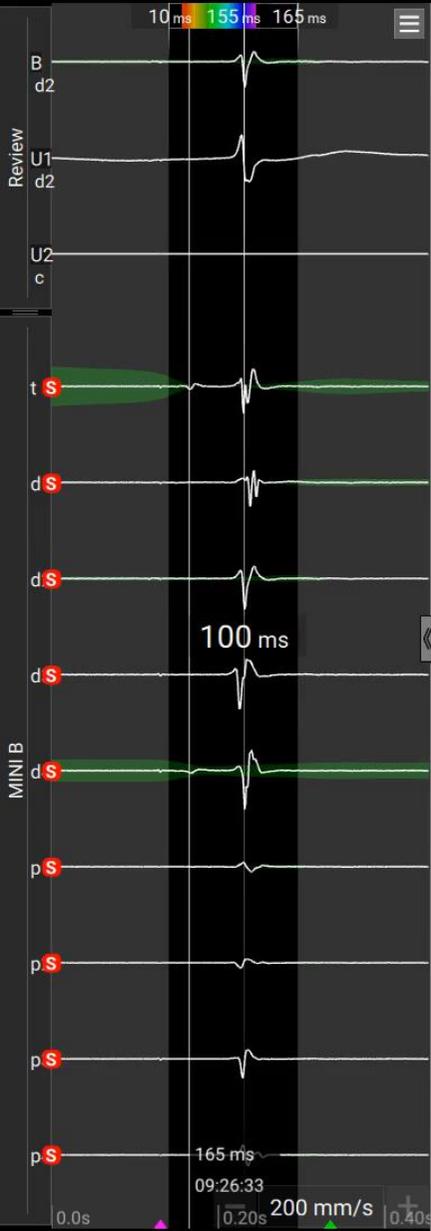
IKEM Case

Ipsilateral PV Isolation with PF Ablation Only

Total PF Time: 2 min 50 sec

Ablation Procedure Time: 15 min

PAF
(68 yrs, Male)



PA Projection

RAO Projection

Close Unipolar Activation Map

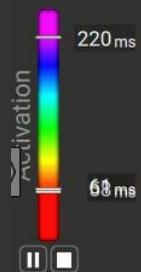
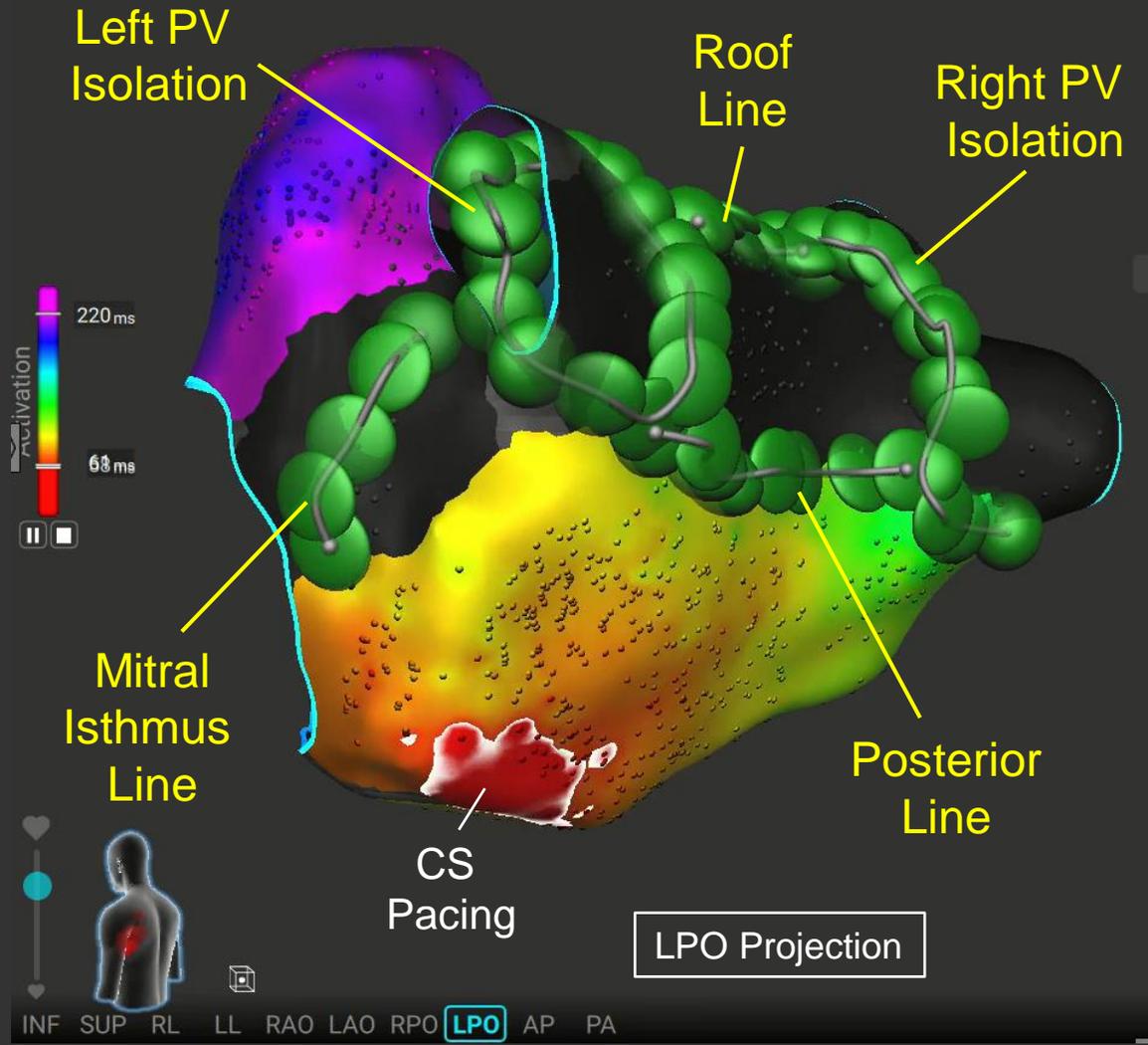
Close Unipolar Activation Map

Persistent AF
(72 yrs, Male)

+ LA-Pace Interval ⚙️
+ ant (0) ⚙️

Post - PF Ablation

IKEM Case



LPO Projection

INF SUP RL LL RAO LAO RPO **LPO** AP PA

Ipsilateral PV Isolation

RF/PF Ablation
(n=40)

PF Only Ablation
(n=36)

Success with Lattice Tip Only	40/40 pts (100%)	36/36 pts (100%)
No. of RF	19.1±5.1	
Total RF Time	1.6±0.4 min	
No. of PF	28.4±14.1	53.1±14.2
Total PF Time	1.8±0.9 min	3.2±0.9 min
Ablation Procedure Time	23.3±9.5 min	22.0±6.8 min

LA Roof Line

RF/PF Ablation
(n=18)

PF Only Ablation
(n=16)

Success with Lattice Tip Only

18/18 (100%)

16/16 (100%)

No. of RF Applications

2.9±2.7

Total RF Time

0.2±0.2 min

No. of PF Applications

1.7±3.1

5.8±3.2

Total PF Time

0.1±0.2 min

0.4±0.2 min

Ablation Procedure time

2.2±3.1 min

1.4±0.7 min

Mitral Isthmus Line

RF/PF Ablation
(n=5)

PF Ablation
(n=9)

Successful Linear Lesion	5/5 (100%)	9/9 (100%)
Success with Lattice Tip Only	4/5 (80%)	9/9 (100%)
No. of Pts with CS Lesions	1/5 (20%)	6/9 (67%)
No. of RF Applications	11.2±4.2	1.2±3.7
Total RF time	1.2±0.5 min	0.1±0.4 min
No. of PF Applications	1.2±2.7	10.9±4.0
Total PF time	0.1±0.3 min	0.8±0.3 min
Ablation Procedure Time	7.8±4.3 min	3.5±1.8 min

Safety Observation

- Stroke, Pericardial Tamponade, Phrenic Nerve Paralysis 0/76 pts
- Vascular Complications 5/76 (6.6%) pts
- PV Stenosis (CTs at 75 ± 11 days) 0/44 pts
- Atrio-esophageal Fistula 0/76 pts
 - Esophageal Erythema RF/PF group 2/36 (5.6%) pts
PF Only Group 0/24 (0%) pts
- Brain MRIs at 1.2 ± 0.6 days:
 - Silent cerebral events (DWI-positive/FLAIR-negative) 5/51 (9.8%) pts
 - Silent cerebral lesions (DWI-positive/FLAIR-positive) 3/51 (5.9%) pts

SUMMARY

- In this First-in-Man Trial, the expandable lattice ablation electrode with large effective surface area using either a combined RF/PF approach or an only PF approach safely and rapidly created lines of conduction block for ipsilateral PV isolation and across the mitral isthmus, LA roof and cavo-tricuspid isthmus
- Real-time vector mapping effectively provided local activation direction during mapping and ablation, with rapid recognition of conduction block and identification and localization of any gap in the ablation line

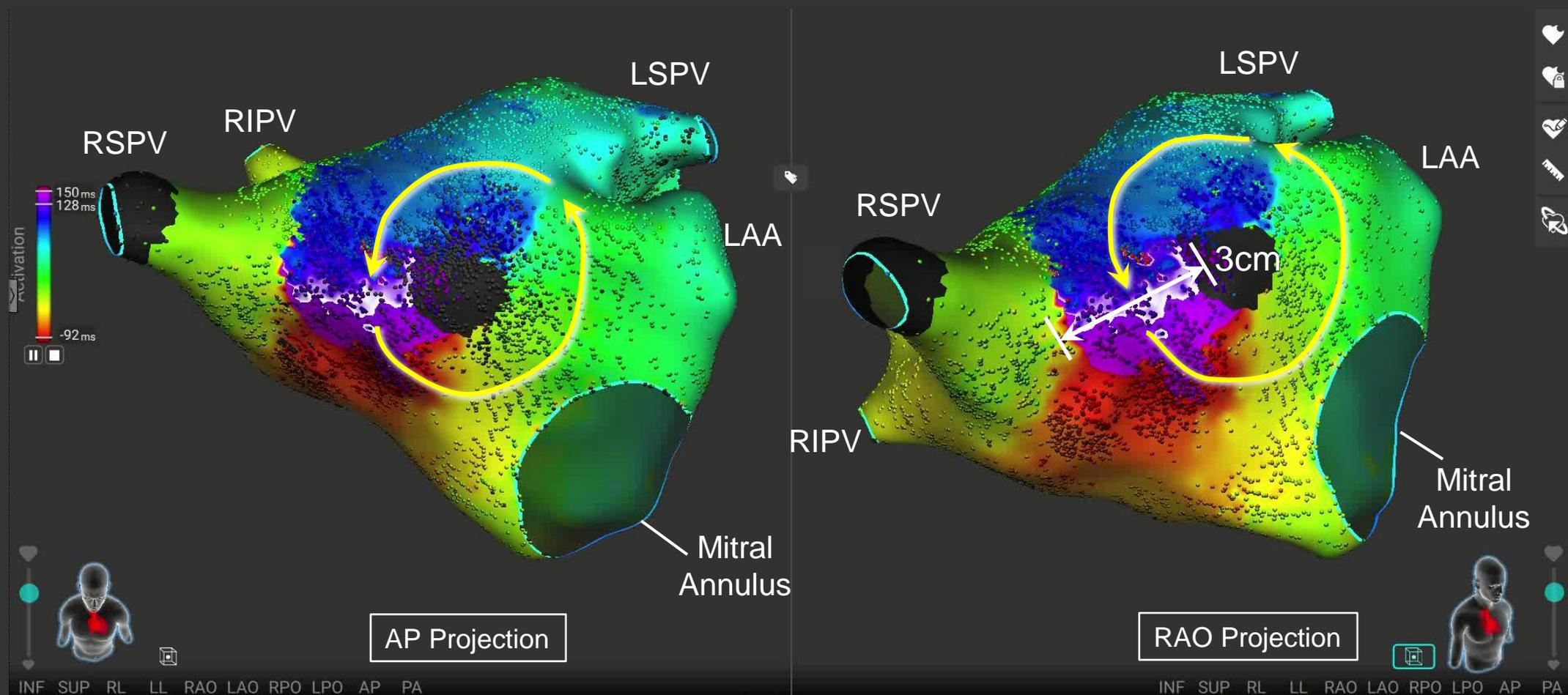
“All in One” Catheter Mapping/Ablation System

Biophysics of Pulsed Field Ablation

Determinants of Pulsed Field Ablation Lesion Size

- Voltage/Current
- Pulse Width
- Duty Cycle / Application Time
- Contact Force/ Electrode-Tissue Coupling
 - 7Fr, 4mm PF Ablation Electrode
 - Constant PF Current/ Application Time
 - Contact Force (5g -40g)
 - LV lesion depth increased significantly with increasing contact force (Depth: 3mm – 7.8mm)
 - No detectable lesions *without* electrode contact (2mm away from the endocardium)

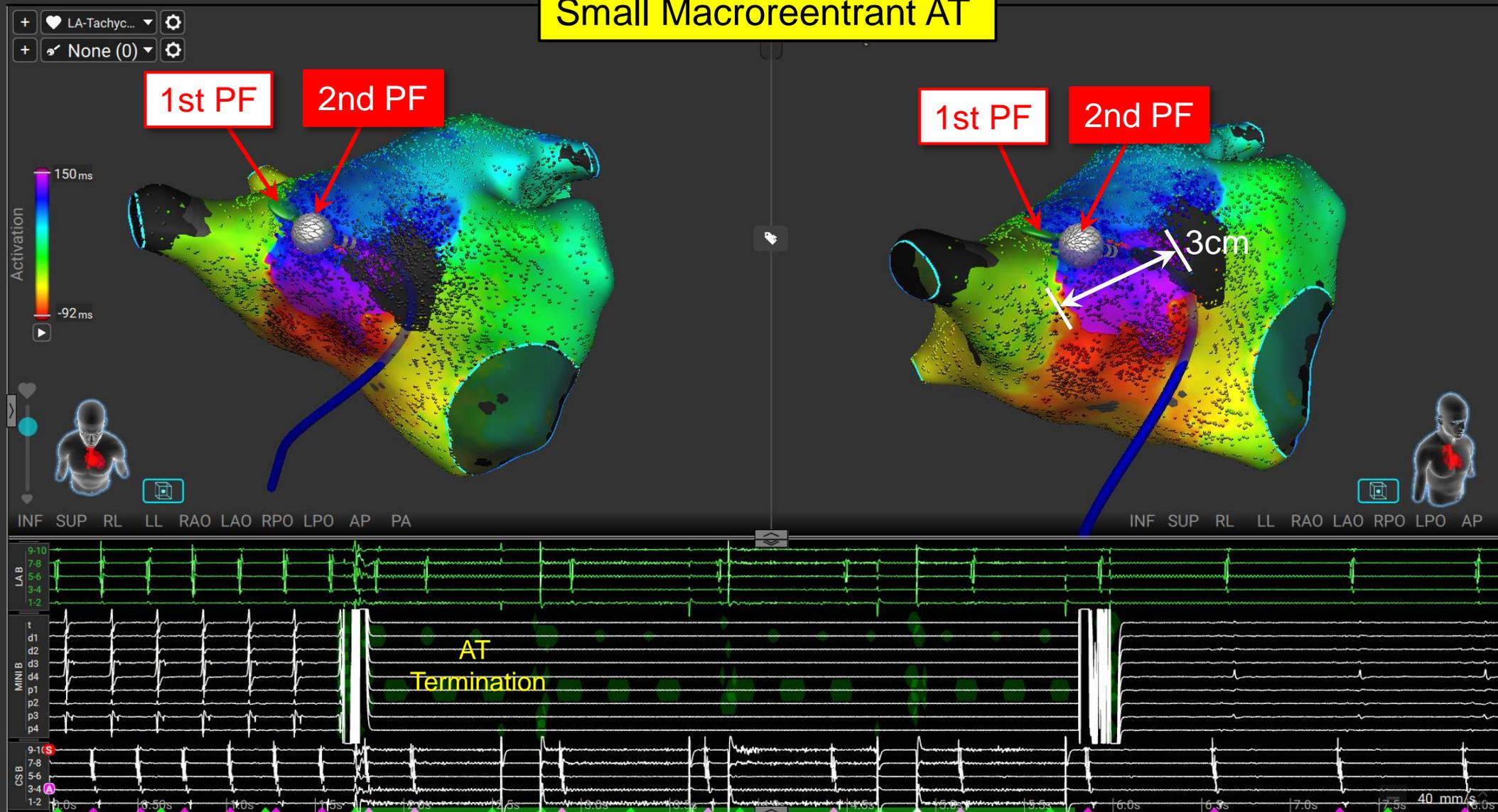
Small Macroreentrant AT



IKEM Case

High-Density Close Unipolar Activation Map

Small Macroreentrant AT



Biophysics of Pulsed Field Ablation

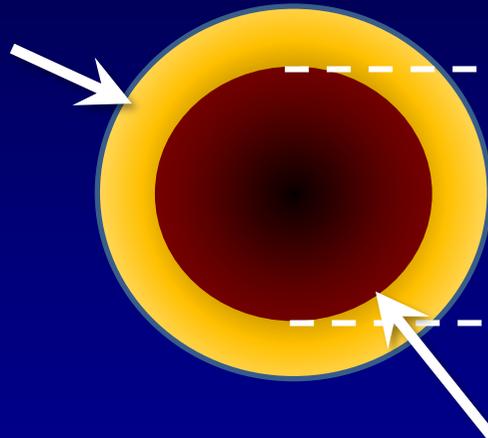
- Irreversible vs. Reversible Zone

RF Ablation

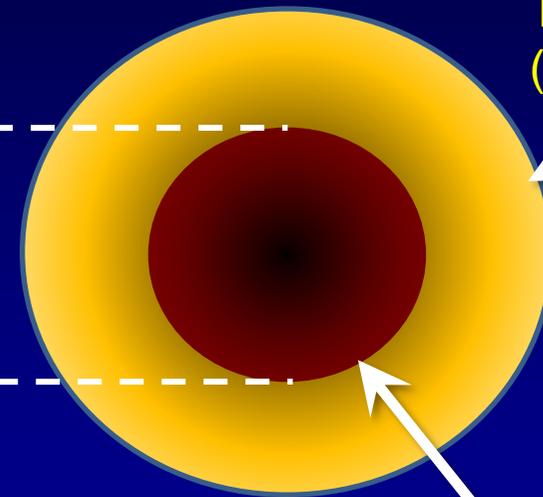
Pulsed Field Ablation

Thermal Injury

Reversible Zone
(Transient Effect):
Transient Block
With Tissue
Temperature of
49.5-51.5°C



Irreversible Zone
(Durable Lesion):
Permanent Conduction Block
with Tissue Temperature of
Median 53.8°C (51.7-54.4°C)



Reversible Zone
(Transient Effect)

Irreversible Zone
(Durable Lesion)

Small Macroreentrant AT

5 PFs
(25 sec)

5 PFs
(25 sec)

