

# PLACE



PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

**ROMA**

Centro Congressi  
di Confindustria

Auditorium  
della Tecnica

9<sup>a</sup> Edizione

**30 Settembre**

**1 Ottobre**

**2022**

**QUALE LAMA PER SCONFIGGERE  
LA FIBRILLAZIONE ATRIALE**

**Rf Balloon per il trattamento  
della FA parossistica :  
efficienza ed efficacia**



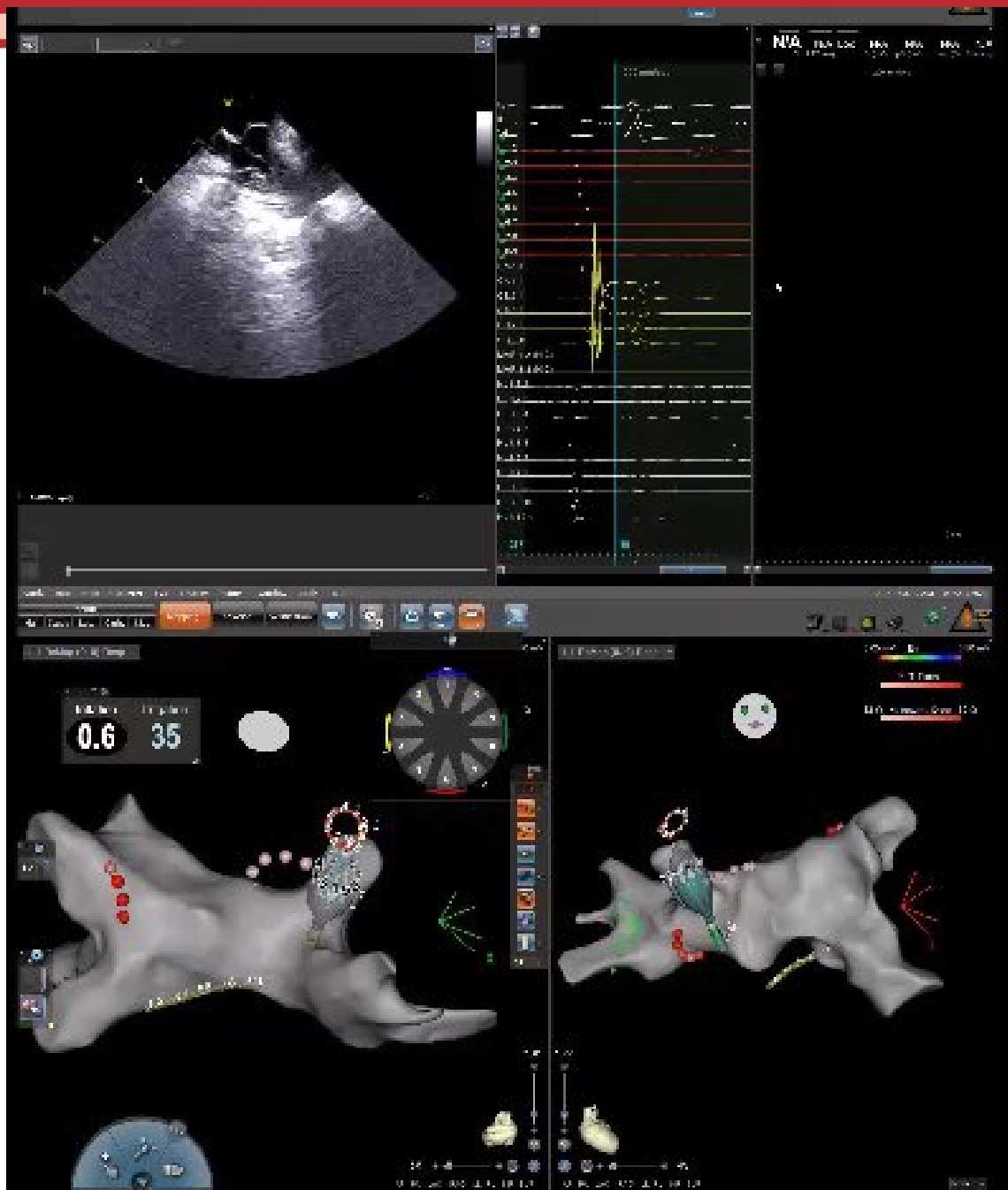


# Disclosures

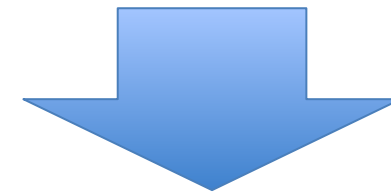
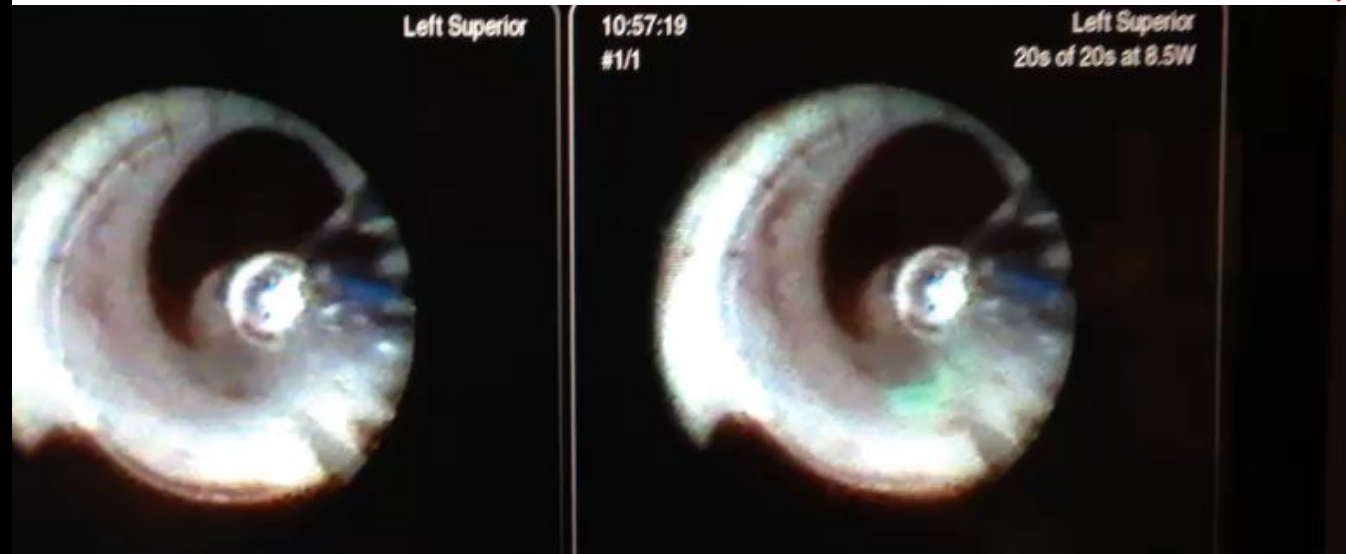
Biosense Webster speaker honoraria

Boston Scientific Proctor for Polarx and Watchman

Abbott Proctor for LAAC



nica



te ablativa indipendentemente  
ta dalla tecnologia a pallone

# First Human experience at CCM Milan



<sup>†</sup> Video recorded during a SHINE (NCT03437733) study case



# CLINICAL STUDIES

STUDY NAME	RADIANCE	SHINE <sup>§</sup>	STELLAR <sup>§</sup>
Study Type	Feasibility	CE-Mark	Pivotal IDE
Study Period	Nov 2016 – Jun 2017	Feb 2018 – May 2020	Oct 2018 – ongoing
Study Design	Prospective, multicenter, single-arm	Prospective, multicenter, single-arm	Prospective, multicenter, single-arm
Investigational Devices	HELIOSTAR™	HELIOSTAR™, LASSOSTAR™	HELIOSTAR™, LASSOSTAR™
Study Population	Adult patients with symptomatic paroxysmal AF (n=39)	Adult patients with symptomatic paroxysmal AF (n=95) ○ Roll-ins n=8	Adult patients with symptomatic paroxysmal AF ○ n=397 (estimated)
Follow-Up Period	3 months	12 months	12 months
Primary Endpoint(s)	○ Safety – Occurrence of Primary AE within 7 days of procedure	○ Safety – incidence of early-onset primary AE ○ Effectiveness – acute success (confirmed entrance block in treated PV after adenosine/isoproterenol challenge)	○ Safety – Primary AEs occurring within 7 days of procedure ○ Effectiveness – Freedom from documented asymptomatic and symptomatic AF/AT/AFL

§ ClinicalTrials.gov Identifier: NCT03437733 (SHINE), NCT03683030 (STELLAR)

# PROCEDURAL EFFICIENCY

ENDPOINT	RADIANCE <sup>1,2</sup>	SHINE <sup>3</sup>
Procedure Time	101.6 ± 29.4 min	87.6 ± 22.3 min
Left Atrial Balloon Dwell Time	40.5 ± 11.5 min	40.3 ± 16.7 min
Fluoroscopy Time	17.4 ± 10.1 min	10.9 ± 9.1 min
Single-Shot Isolation Rate	79.6 %	73.9 %
Time to PV Isolation by Real-Time EGM*	NA	LIPV: 10.9 ± 9.8 sec LSPV: 12.6 ± 11.8 sec RIPV: 9.1 ± 4.8 sec RSPV: 10.4 ± 8.4 sec
Number of RF Applications	LIPV: 1.8 ± 1.2 LSPV: 1.9 ± 1.3 RIPV: 2.0 ± 0.9 RSPV: 1.7 ± 0.8	LIPV: 2.0 ± 1.5 LSPV: 2.1 ± 1.8 RIPV: 1.7 ± 1.0 RSPV: 1.8 ± 1.5

\* Defined as the observed RF ablation time to reach isolation by one ablation application; EGM, electrogram.

1. Reddy V et al. "PV Isolation with a Novel Multielectrode Radiofrequency Balloon Catheter that Allows Directionally-Tailored Energy Delivery: Short-Term Outcomes from a Multicenter First-in-Human Study (RADIANCE)" *Circ Arrhythm Electrophysiol* 2019 Dec; 12(12):e007541.

2. Dhillon G et al. "Use of a multi-electrode radiofrequency balloon catheter to achieve pulmonary vein isolation in patients with paroxysmal atrial fibrillation: 12-Month outcomes of the RADIANCE study" *J Cardiovasc Electrophysiol*. 2020 Jun;31(6):1259-1269.

3. Schilling R et al. "Safety, effectiveness, and quality of life following pulmonary vein isolation with a multi-electrode radiofrequency balloon catheter in paroxysmal atrial fibrillation: 1-year outcomes from SHINE" *Europace*. 2020 Jan 15:euaa382 (E-pub ahead of print)

# ANESTHESIA COMPATIBILITY IN SHINE<sup>1</sup>

Except fluoroscopy and procedure time, procedural efficiency, safety, and treatment outcome data were similar between subjects under general anesthesia vs. conscious sedation

ENDPOINT	GENERAL ANESTHESIA (N = 46)	CONSCIOUS SEDATION (N = 39)	P-VALUE
Mapping time	7.9 ± 5.6 min	5.5 ± 3.0 min	0.06
LA Balloon Dwell Time	36.8 ± 12.9 min	44.5 ± 19.7 min	0.06
Fluoroscopy Time	5.9 ± 4.8 min	16.7 ± 9.6 min	< 0.001
Procedure Time	81.8 ± 19.4 min	94.4 ± 23.7 min	0.008
Acute PVI Success	45/45 (100%)	37/37 (100%)	NA
Primary Adverse Event	0/39 (0%)	1/45 (2.2%)	1.00
12-Month Freedom from Symptomatic Atrial Arrhythmia Recurrence	31/41 (75.6%)	26/38 (68.4%)	0.62

1. Schilling R et al. "Safety, effectiveness, and quality of life following pulmonary vein isolation with a multi-electrode radiofrequency balloon catheter in paroxysmal atrial fibrillation: 1-year outcomes from SHINE" Europace. 2020 Jan 15:euaa382 (E-pub ahead of print)

# SAFETY

ENDPOINT	RADIANCE <sup>1</sup>	SHINE <sup>3</sup>
Primary/Serious Adverse Event	2.6 %	1.2 %
Primary/Serious Adverse Event Detail	Phrenic nerve damage in 1/39 patients during RSPV ablation because phrenic nerve pacing was inadvertently not performed	Vascular access complication (retroperitoneal bleed) in 1/87 patients during introduction of transseptal sheath replacement which was treated conservatively and procedure completed
PV Stenosis	0 %	0 %
Atrio-Esophageal Fistula	0 %	0 %
Silent Cerebral Lesion	23.7 % <sup>2</sup>	9.7 %

1. Reddy V et al. "PV Isolation with a Novel Multielectrode Radiofrequency Balloon Catheter that Allows Directionally-Tailored Energy Delivery: Short-Term Outcomes from a Multicenter First-in-Human Study (RADIANCE)" *Circ Arrhythm Electrophysiol* 2019 Dec; 12(12):e007541.

2. Grimaldi M et al. "Impact of workflow modifications in atrial fibrillation ablation for reducing the incidence of silent cerebral lesions with a new multi-electrode radiofrequency balloon catheter" *Eur Heart J* 2019 Oct; 40 (Supp 1): 624.

3. Schilling R et al. "Safety, effectiveness, and quality of life following pulmonary vein isolation with a multi-electrode radiofrequency balloon catheter in paroxysmal atrial fibrillation: 1-year outcomes from SHINE" *Europace*. 2020 Jan 15:euaa382 (E-pub ahead of print)

## EFFECTIVE PVI

ENDPOINT	RADIANCE <sup>1,2</sup>	SHINE <sup>3</sup>
Acute PV Reconnection	4.6 %	9.3 %
Acute PV Reconnection by PV	NA	LIPV: 14.7 % LSPV: 8.0 % RIPV: 7.2 % RSPV: 6.1 %
PVI Success After Adenosine/Isoproterenol Challenge	100 %	100 %
PVI Without Focal Touch-Up	100 %	98.8 %
Freedom from Atrial Arrhythmia Recurrence at 12 Months	Standard-of-Care Monitoring: 86.4 % (On/Off AAD) 75.7 % (Off AAD)	Stringent Monitoring: 72.2 % (Symptomatic Recurrence)

1. Reddy V et al. "PV Isolation with a Novel Multielectrode Radiofrequency Balloon Catheter that Allows Directionally-Tailored Energy Delivery: Short-Term Outcomes from a Multicenter First-in-Human Study (RADIANCE)" *Circ Arrhythm Electrophysiol* 2019 Dec; 12(12):e007541.

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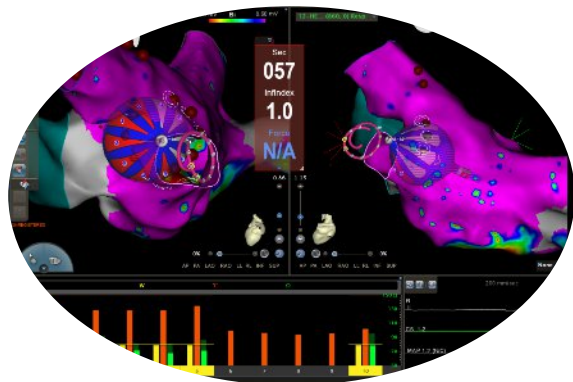
3. Schilling R et al. "Safety, effectiveness, and quality of life following pulmonary vein isolation with a multi-electrode radiofrequency balloon catheter in paroxysmal atrial fibrillation: 1-year outcomes from SHINE" *Europace*. 2020 Jan 15:euaa382 (E-pub ahead of print)



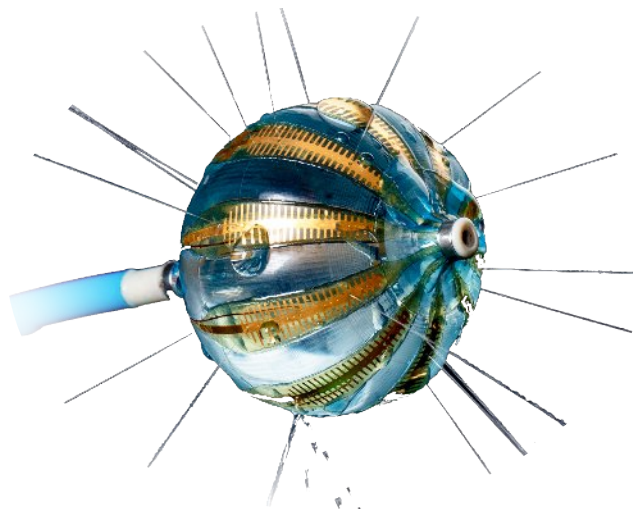
# Safety Reminder

- Anticoagulation should be uninterrupted prior to procedure<sup>1</sup>
- Bolus dosing with Heparin before transseptal puncture
- Maintain ACT ideally at 350-400 sec
- Assemble and prepare catheters and sheath following recommended workflow
- Maximum target temperature should not exceed 35°C

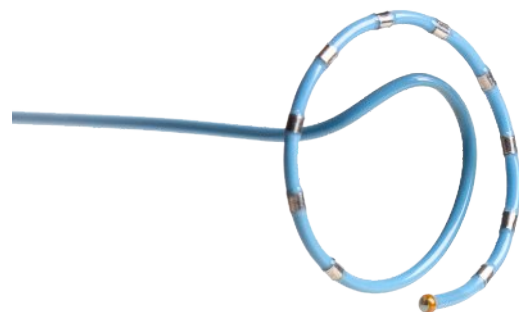
# HELIOSTAR™ BALLOON ABLATION CATHETER PLATFORM OVERVIEW



**CARTO® 3 SYSTEM**



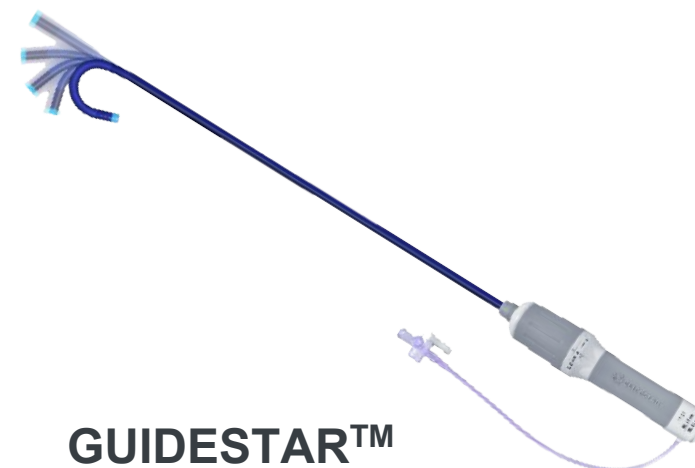
**HELIOSTAR™ BALLOON  
ABLATION CATHETER**



**LASSOSTAR™ CATHETER**

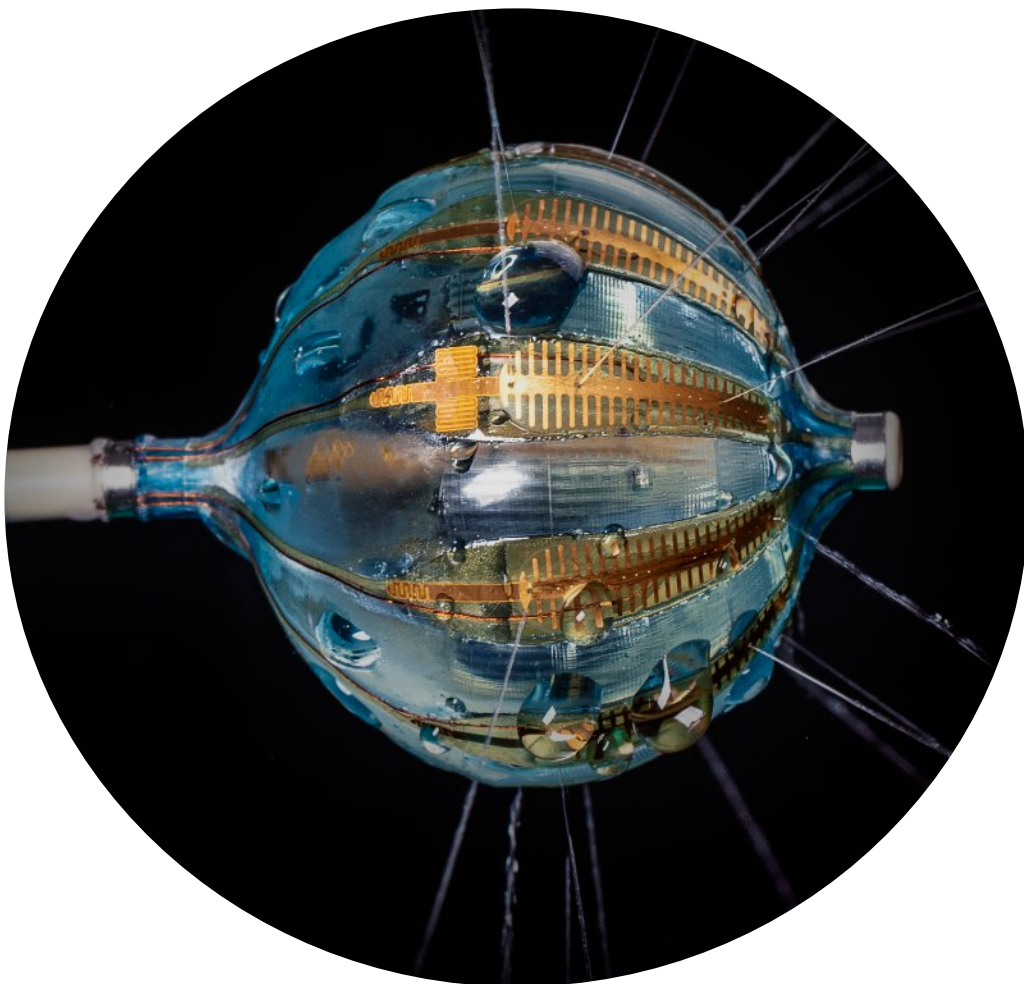


**nGEN™ GENERATOR\***



**GUIDESTAR™  
DEFLECTABLE SHEATH**

# HELIOSTAR™ BALLOON ABLATION CATHETER



- 28mm diameter
- 10 electrodes, with one thermocouple each
- 4 irrigation ports per electrode
- Inner lumen for LASSOSTAR™ Catheter placement, as well as contrast injection
- Radiopaque markers to identify electrodes on fluoroscopy

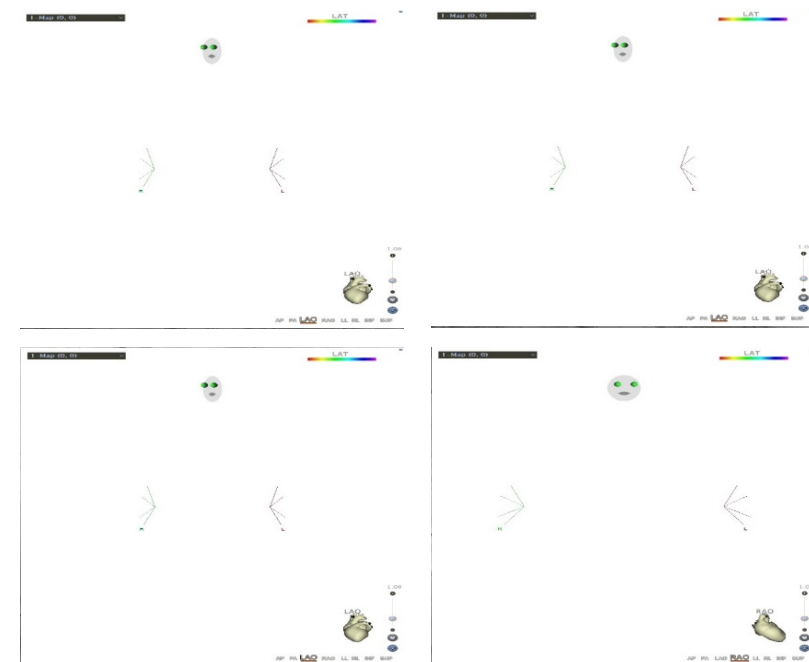
Rectangle Electrode # 1



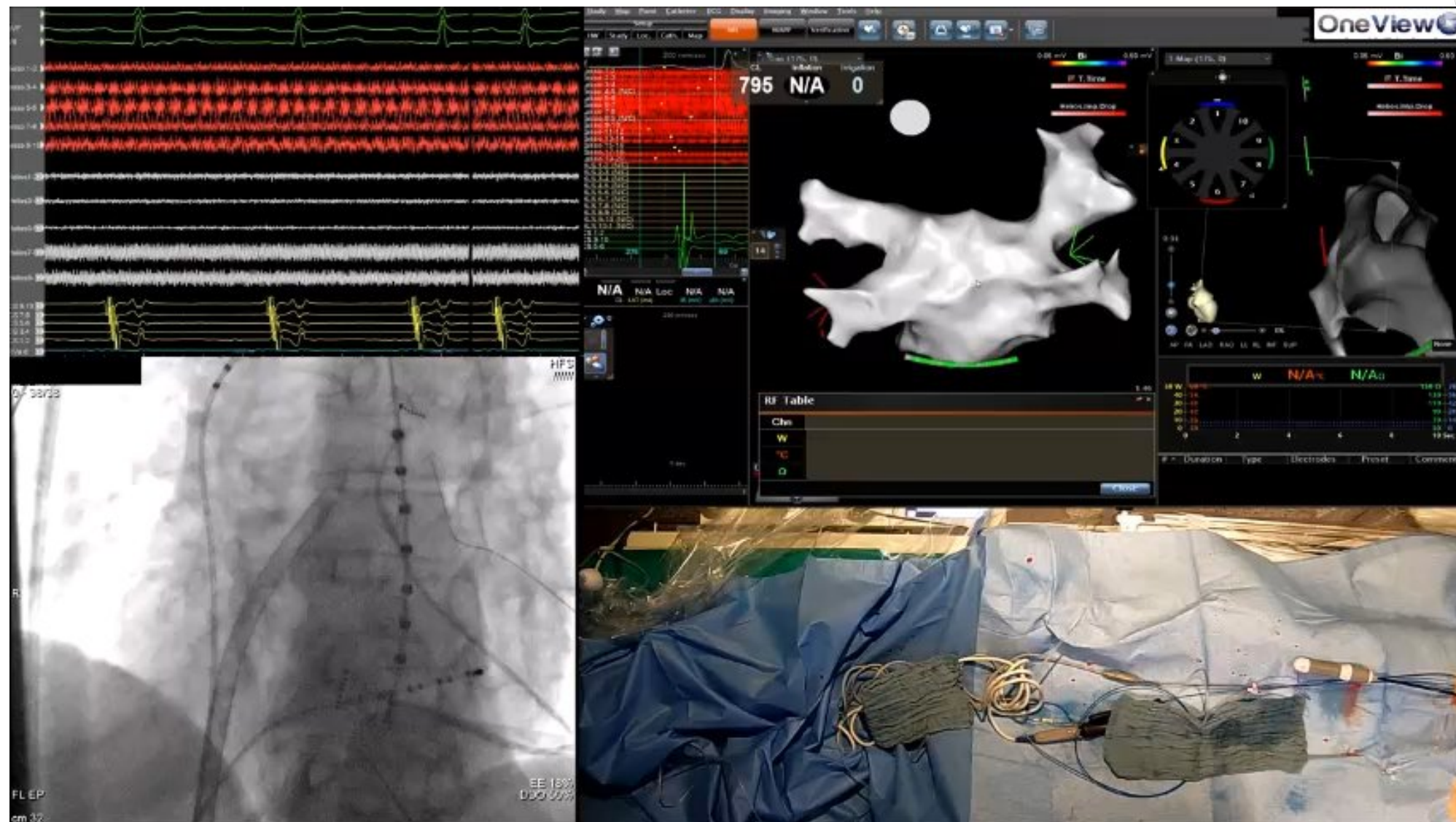
Closed Triangle Electrode # 4



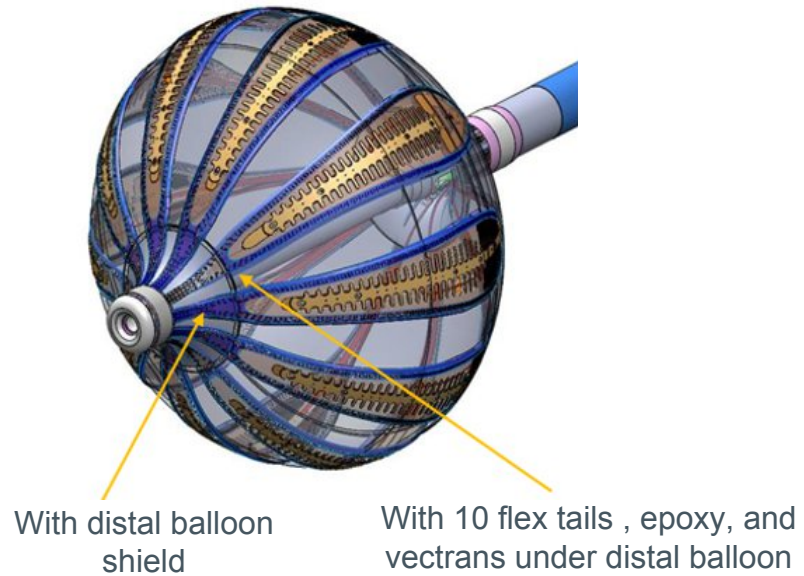
Open Triangle Electrode #7



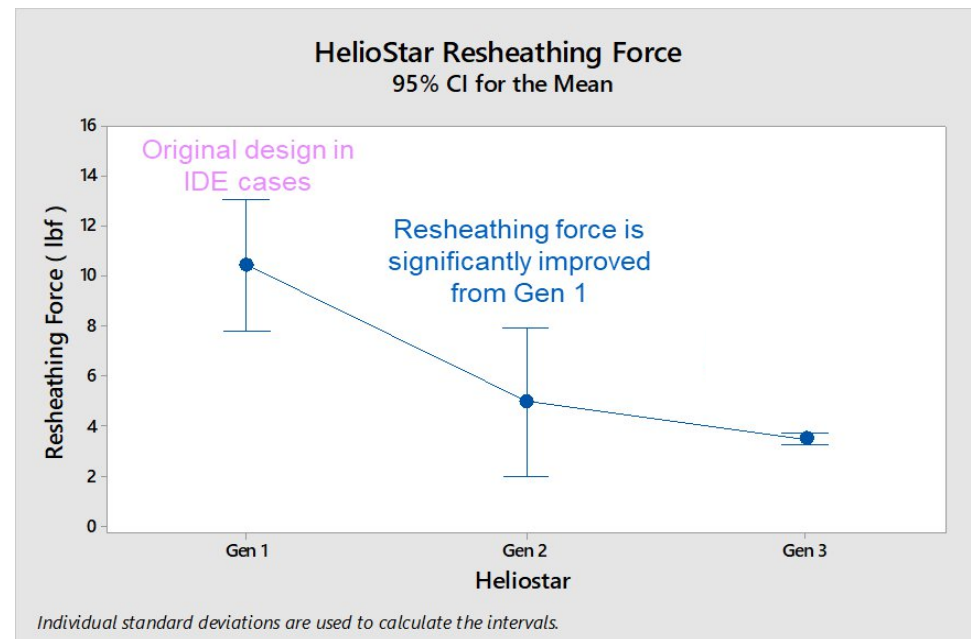
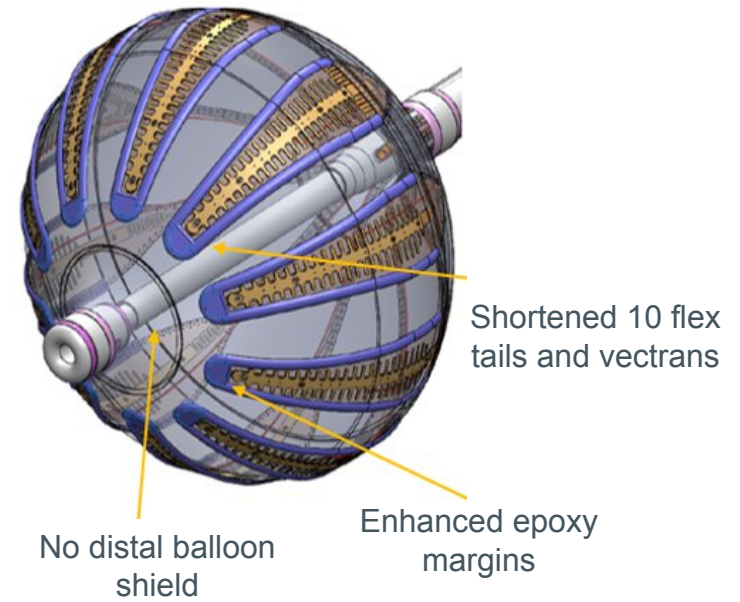




## Gen 2

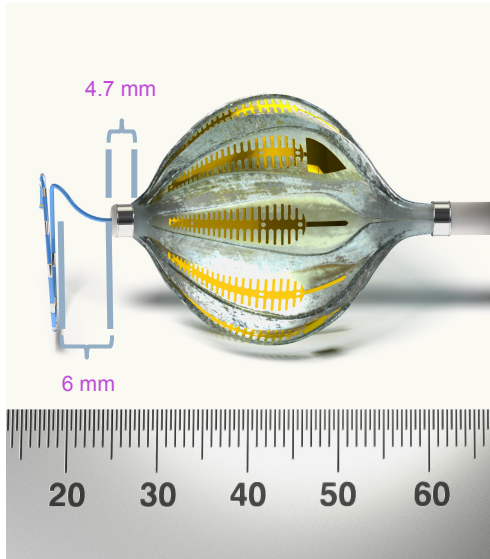


## Gen 3

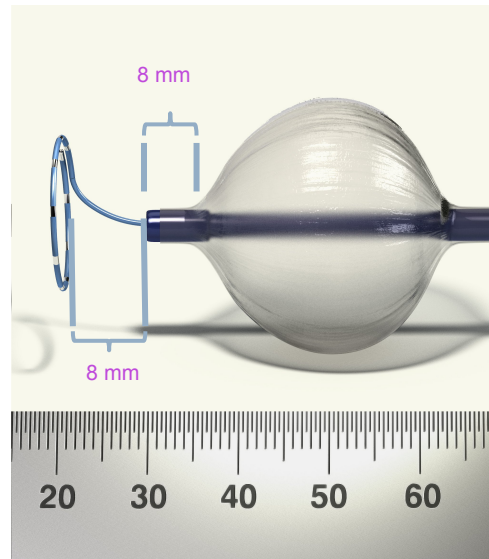




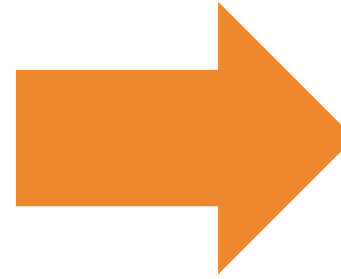
# Mapping Electrodes Closer to Balloon to Monitor PV signals with **LASSOSTAR™ NAV Catheter**



HELIOSTAR™ Balloon Ablation Catheter  
& LASSOSTAR™ NAV Catheter

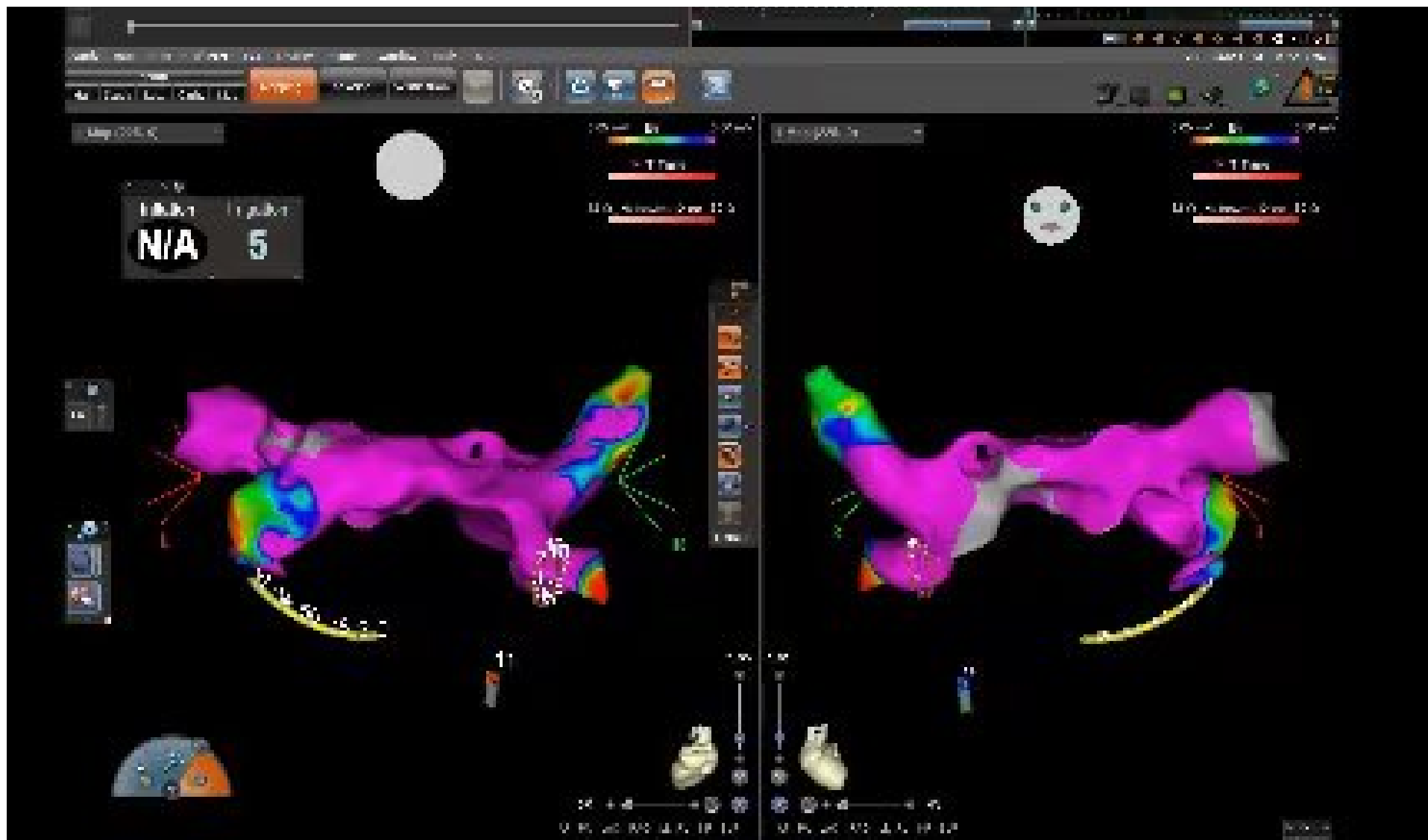


Arctic Front Advance Pro™ Cardiac  
Cryoablation Catheter & Achieve™ Catheter

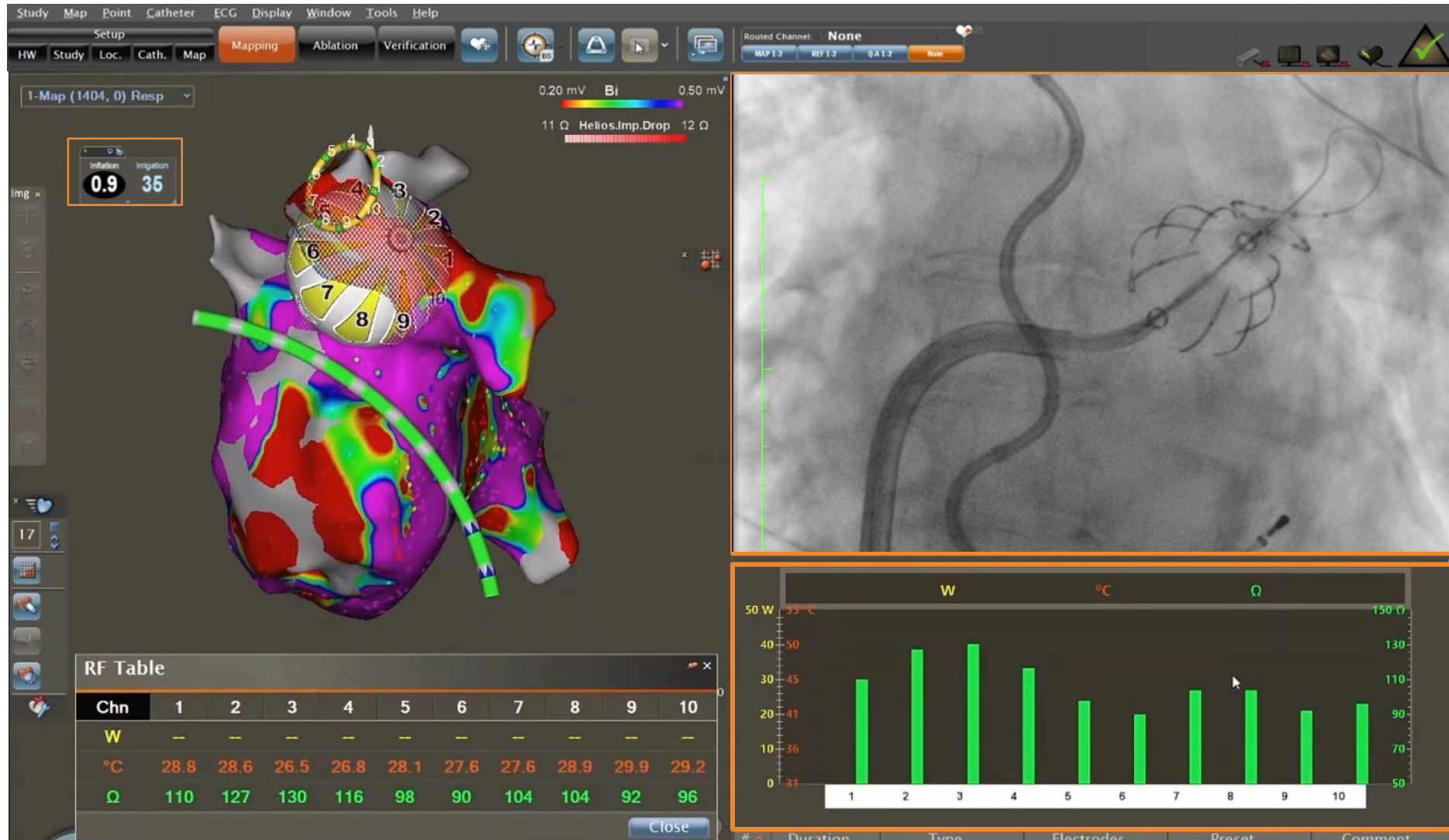


## LASSOSTAR™ NAV Catheter

- 3 French fixed loop
- 10 evenly spaced 1 mm electrodes
- 3 loop diameters
  - 15 mm (4.5 mm spacing)
  - 20 mm (6.0 mm spacing)
  - 25 mm (8.0 mm spacing)
- Inserted through central lumen of HELIOSTAR™ Balloon Ablation Catheter

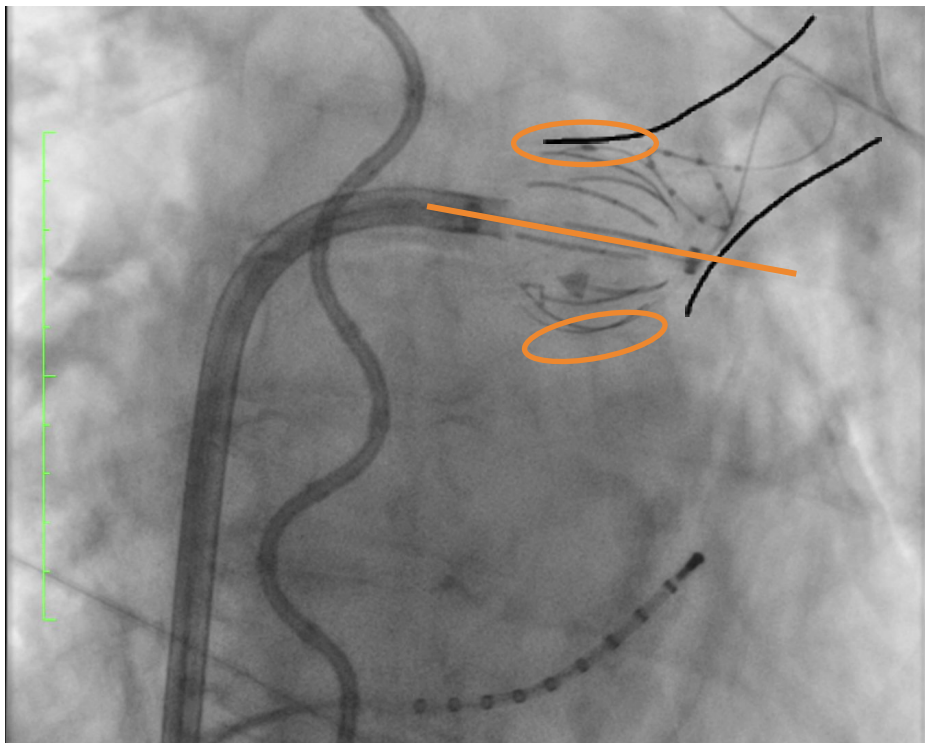


# Optimal Balloon Positioning on CARTO™ 3 System



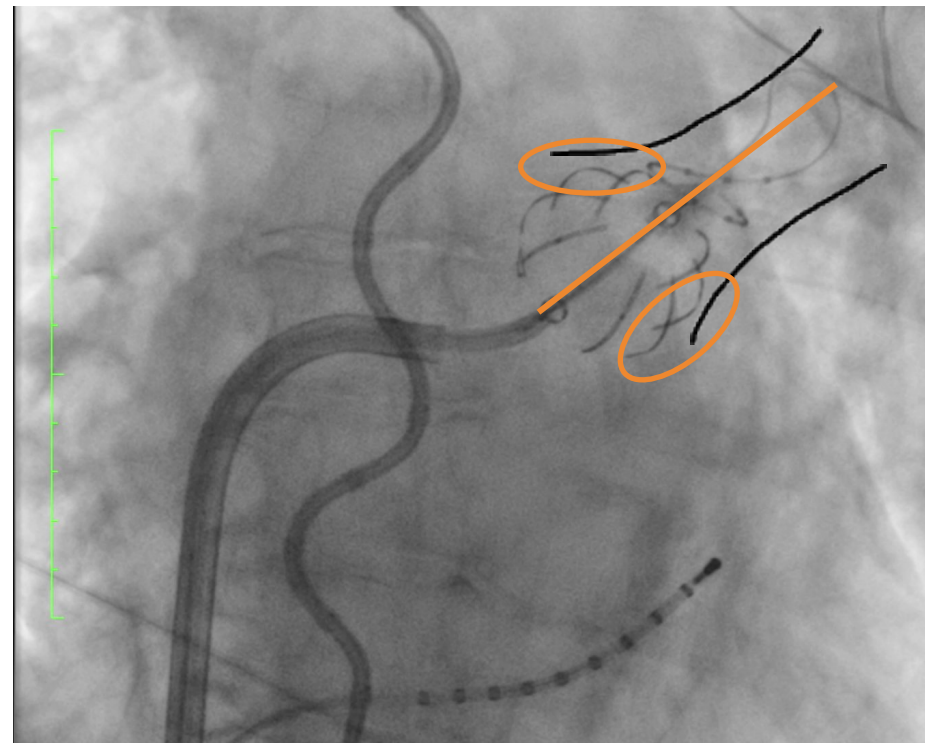
[Play video](#)

# Co-Axial Alignment for Optimal Electrode Contact



*Play video*

Partial Electrode Contact  
with no alignment

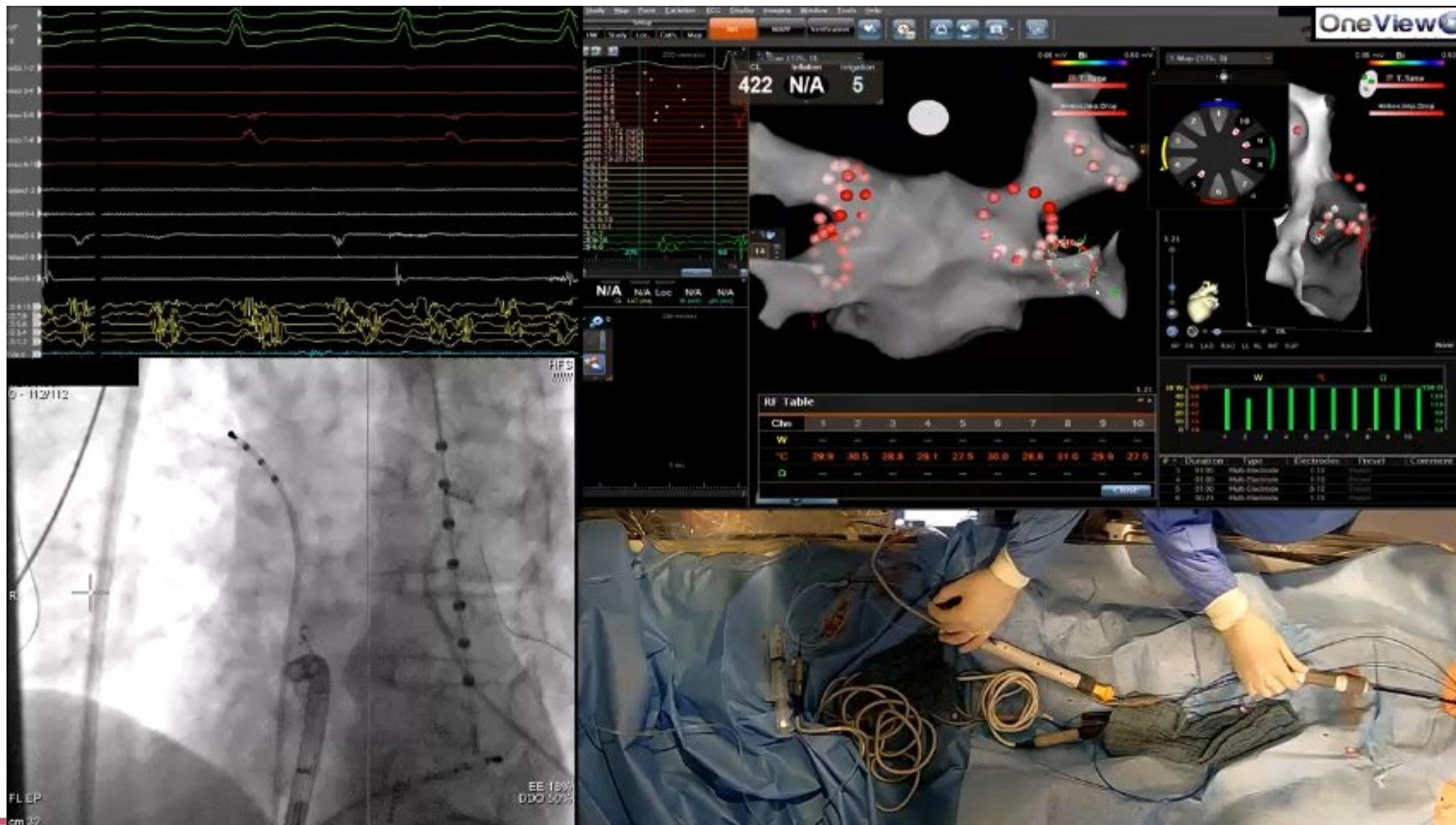


*Play video*

Full electrode contact with  
co-axial alignment



# Troubles.....



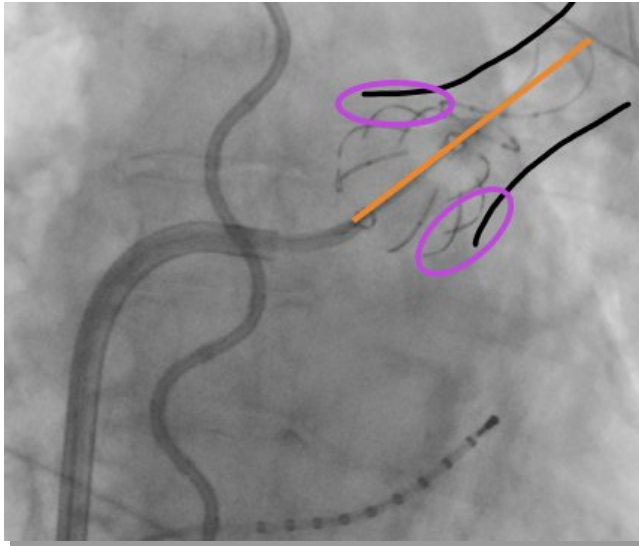


# Criteria for Optimal Balloon Placement

Pre-ablation  
indicators

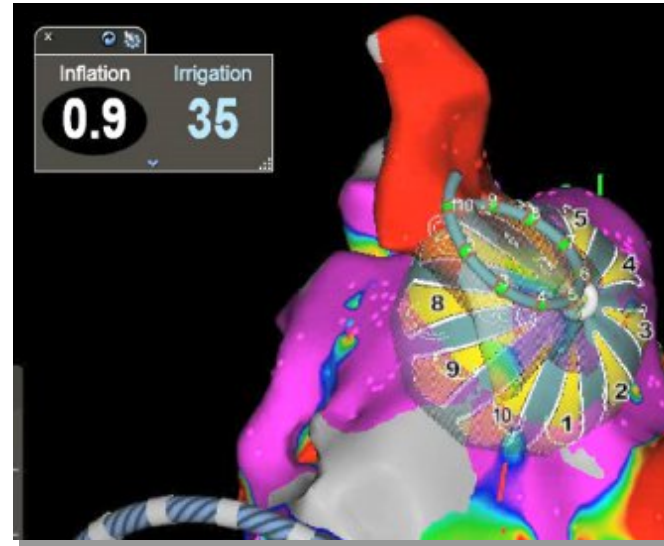
85-130  $\Omega$

Below 31°C



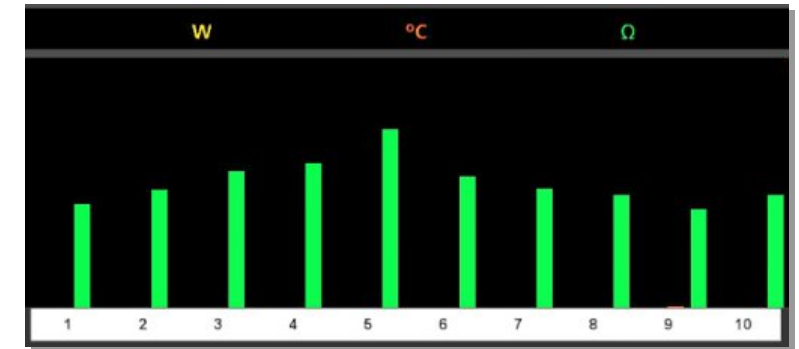
## CO-AXIAL

HELIOSTAR™ Balloon  
Ablation Catheter in axis  
with the vein



## INFLATED

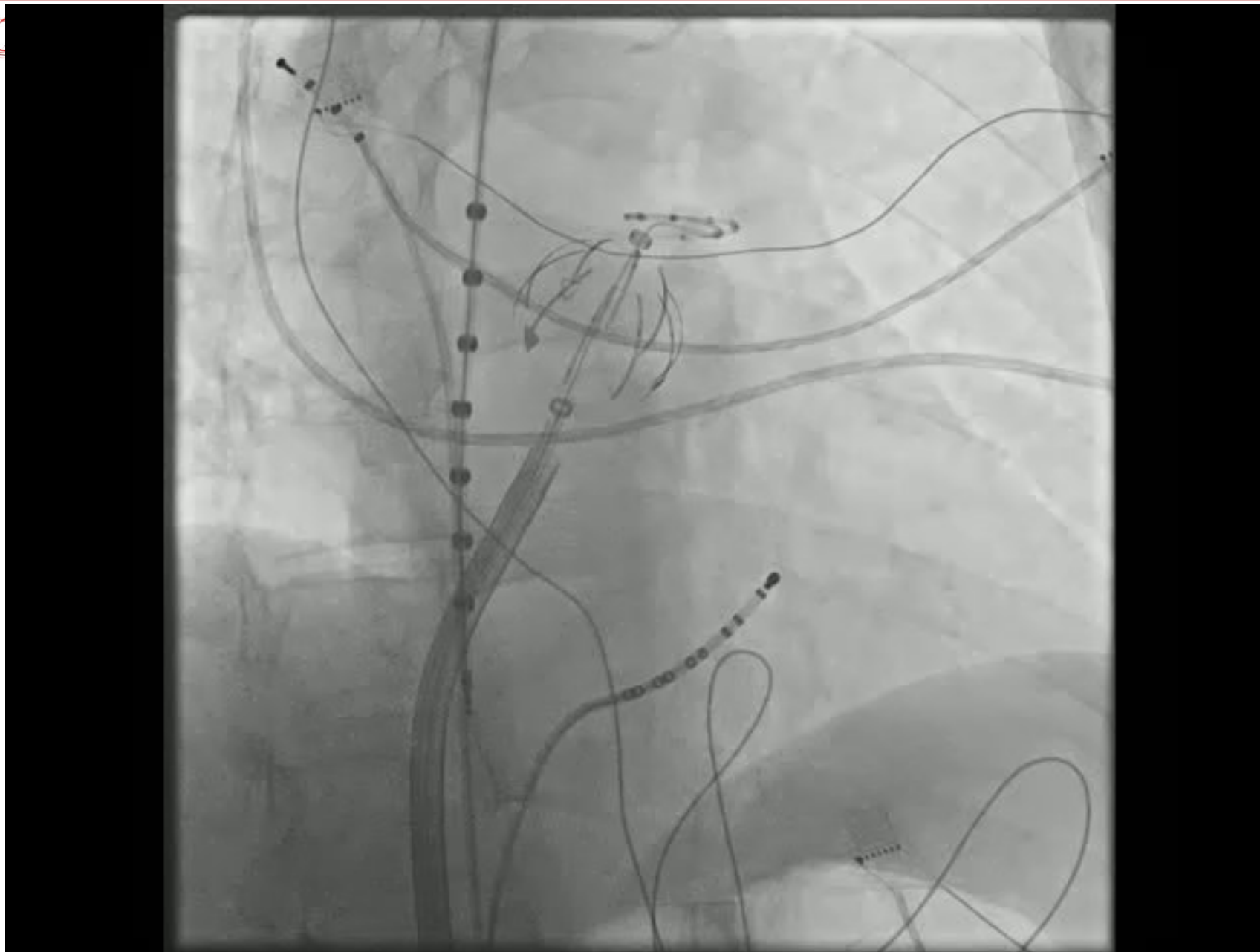
Inflation Index > 0.8<sup>1</sup>



## OPTIMAL BALLOON INDICATORS

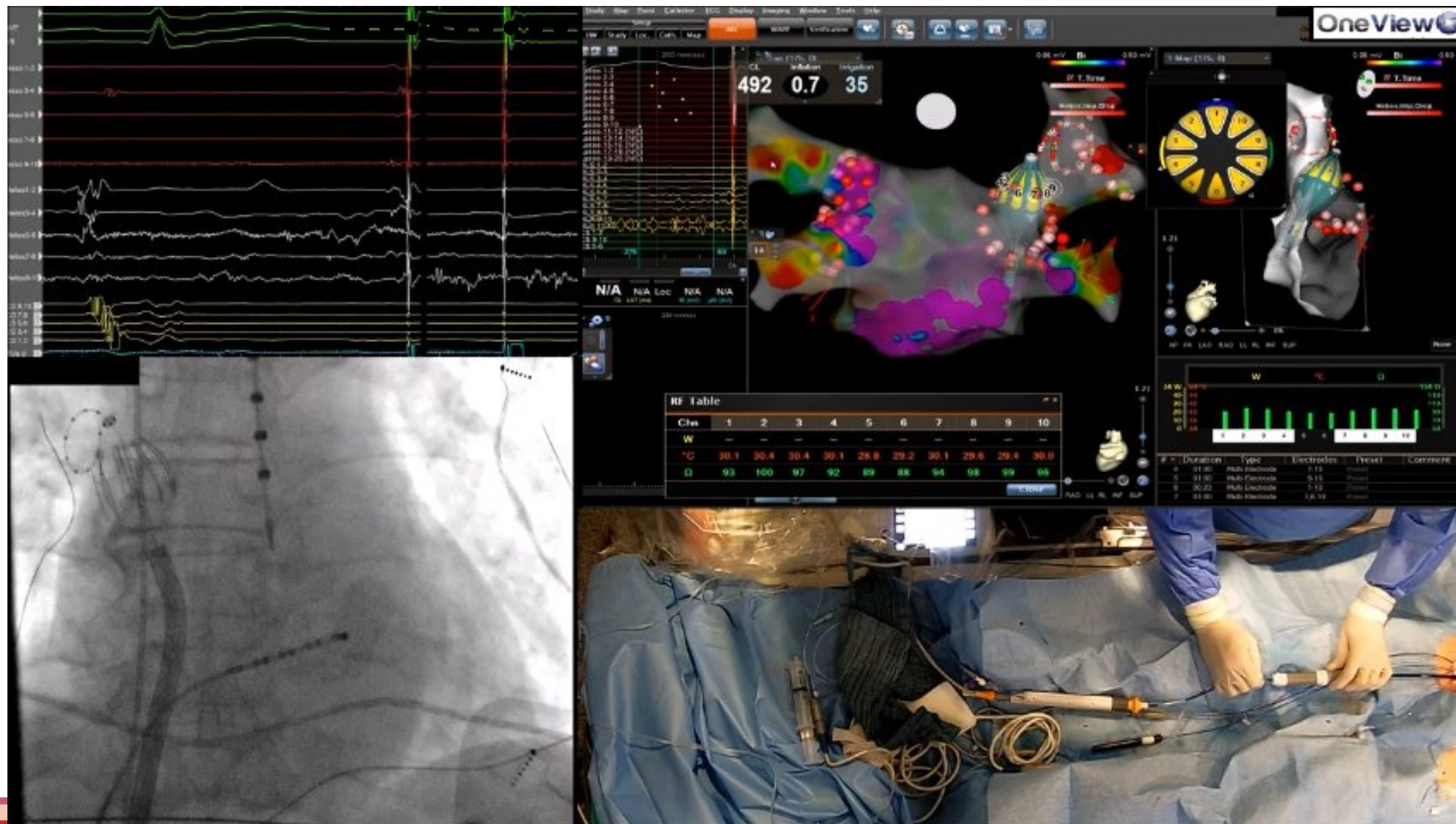
Impedance Range, Temperature  
Max<sup>2</sup>

1 minute unipolar RF pulse; at 20 sec switch off Esop facing  
electrodes

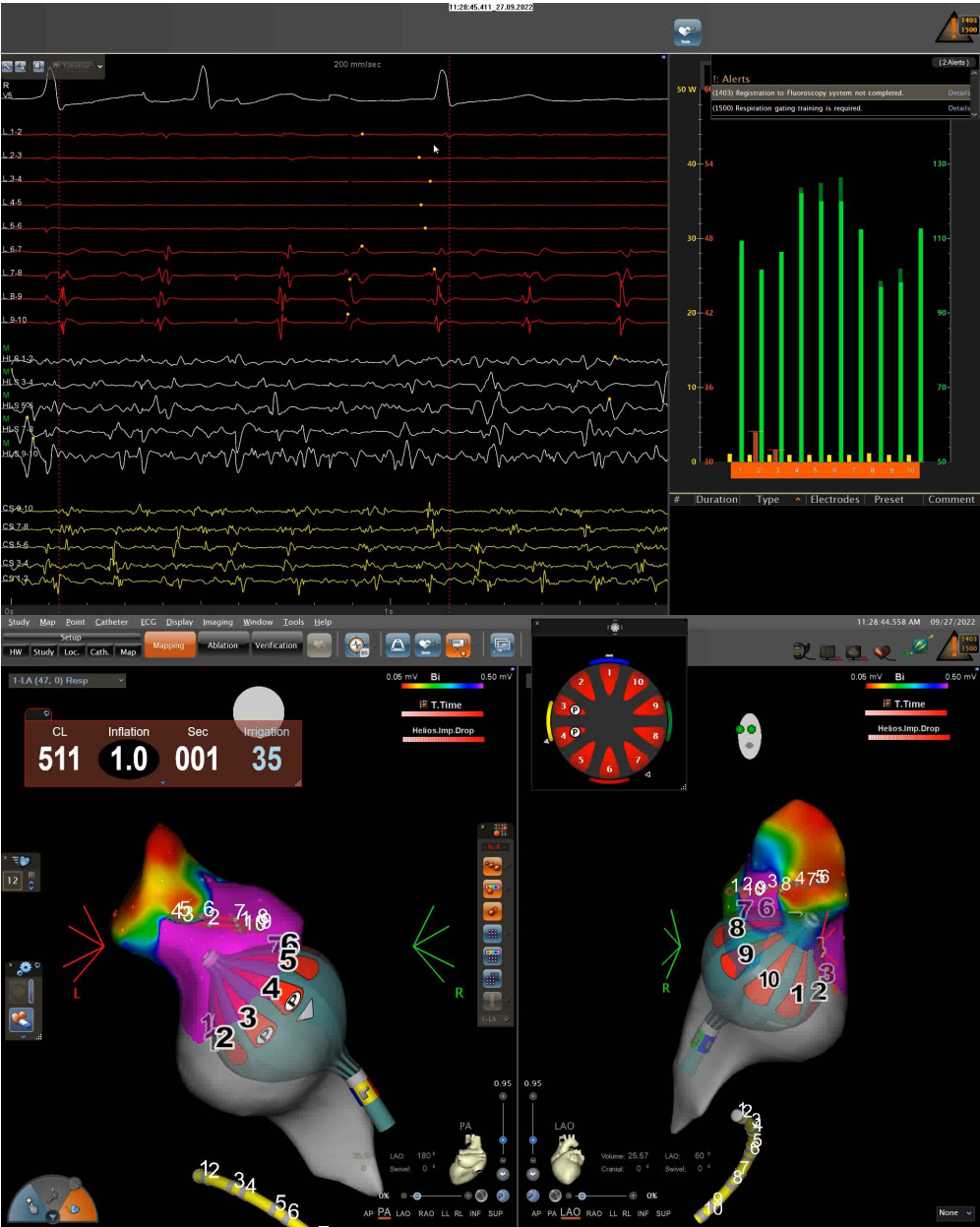


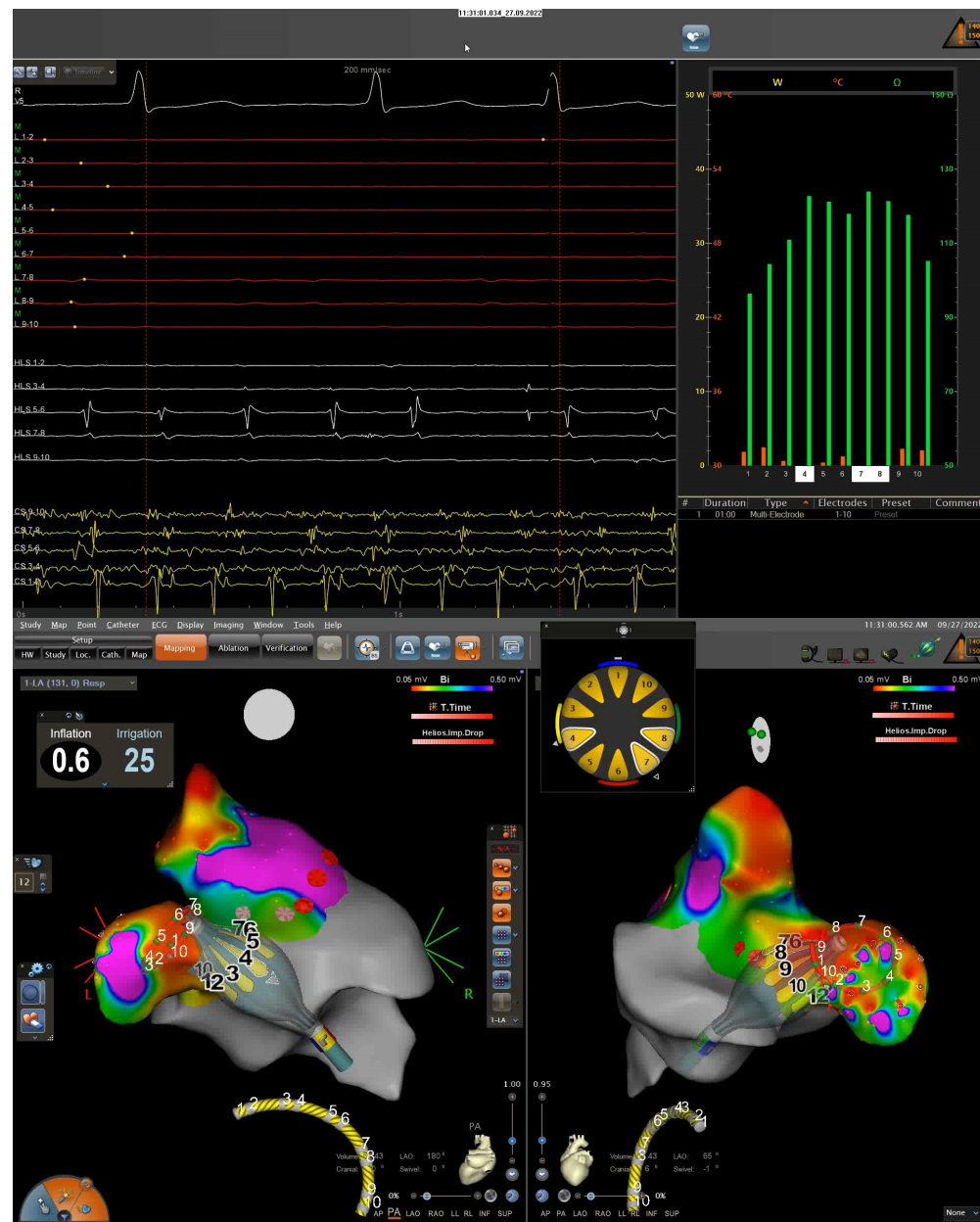


# Disallineamento.....

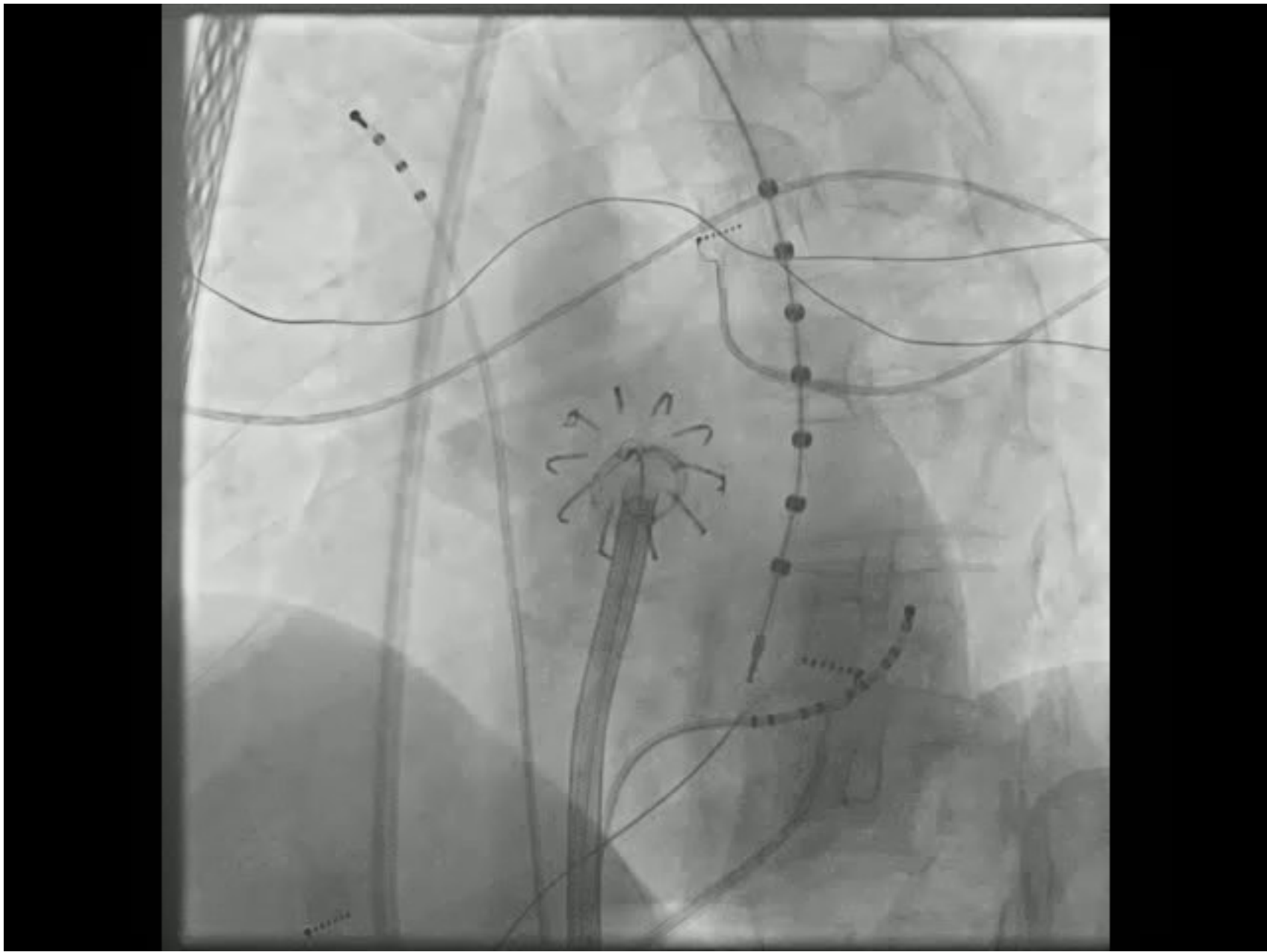


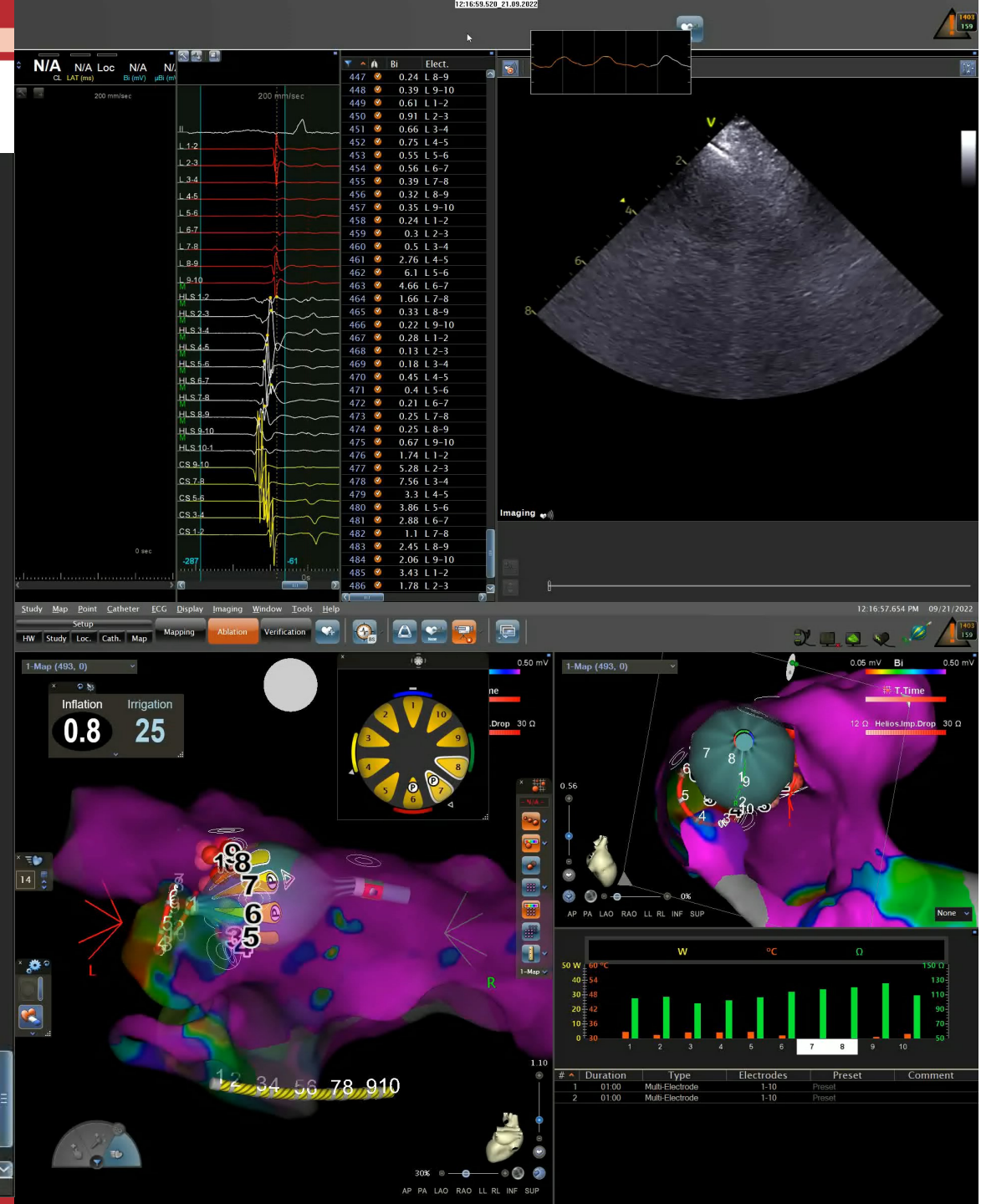
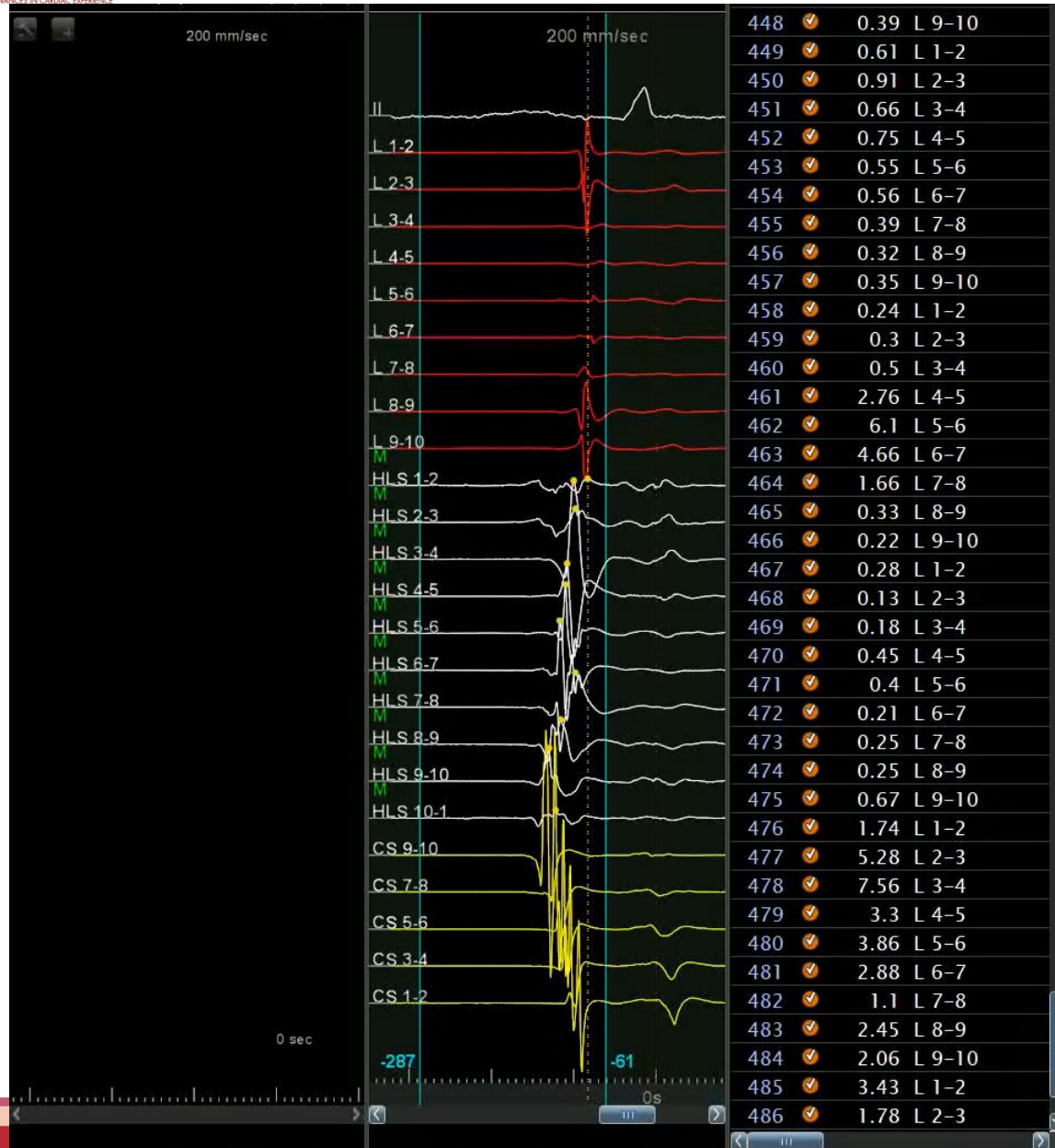




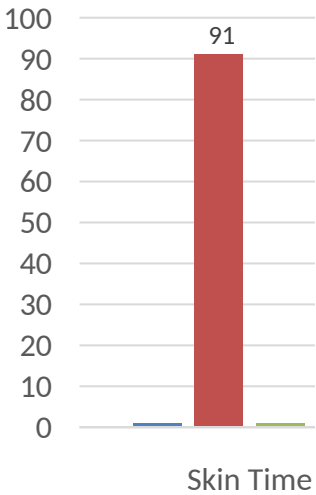




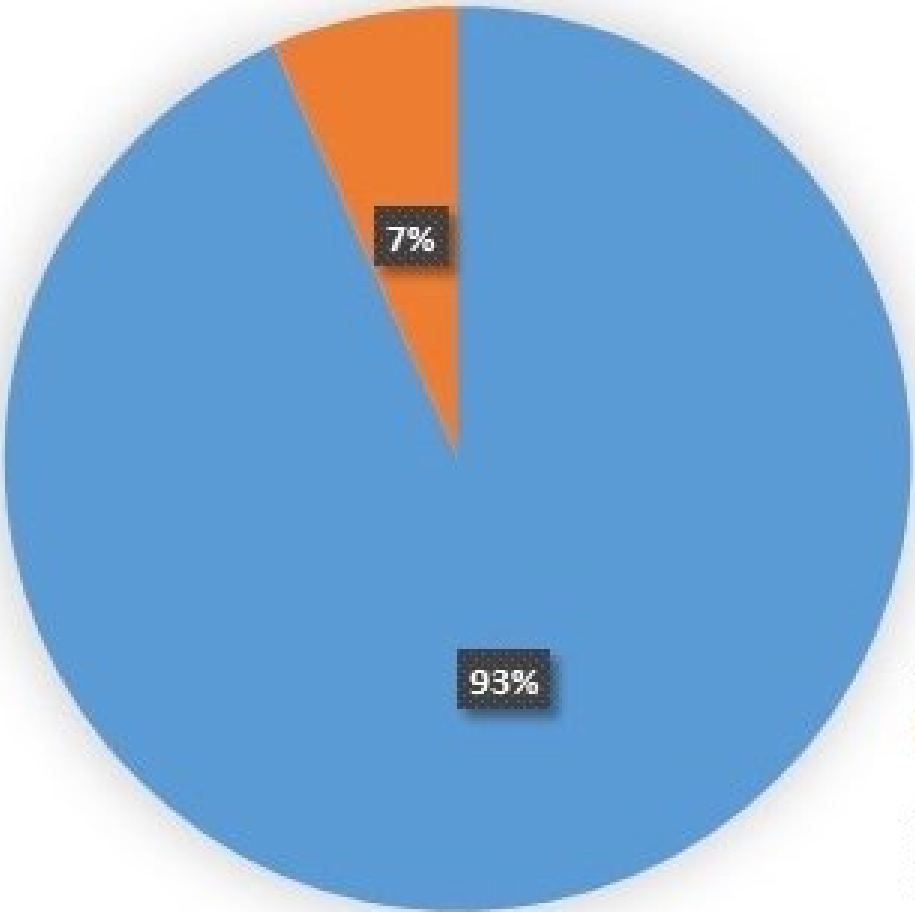




HELIOSTAR™  
With LAS

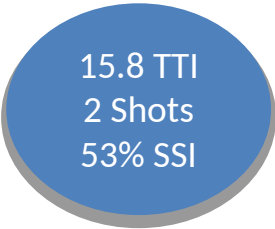


CARDIOLOGICO MONZINO  
FUP range 1-12months median 7

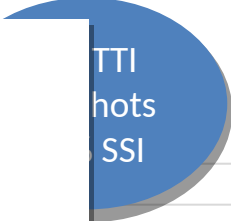


Total 63  
Recurrence 4  
PAF 49  
EarlyPers.AF 14

LSPV



RSPV



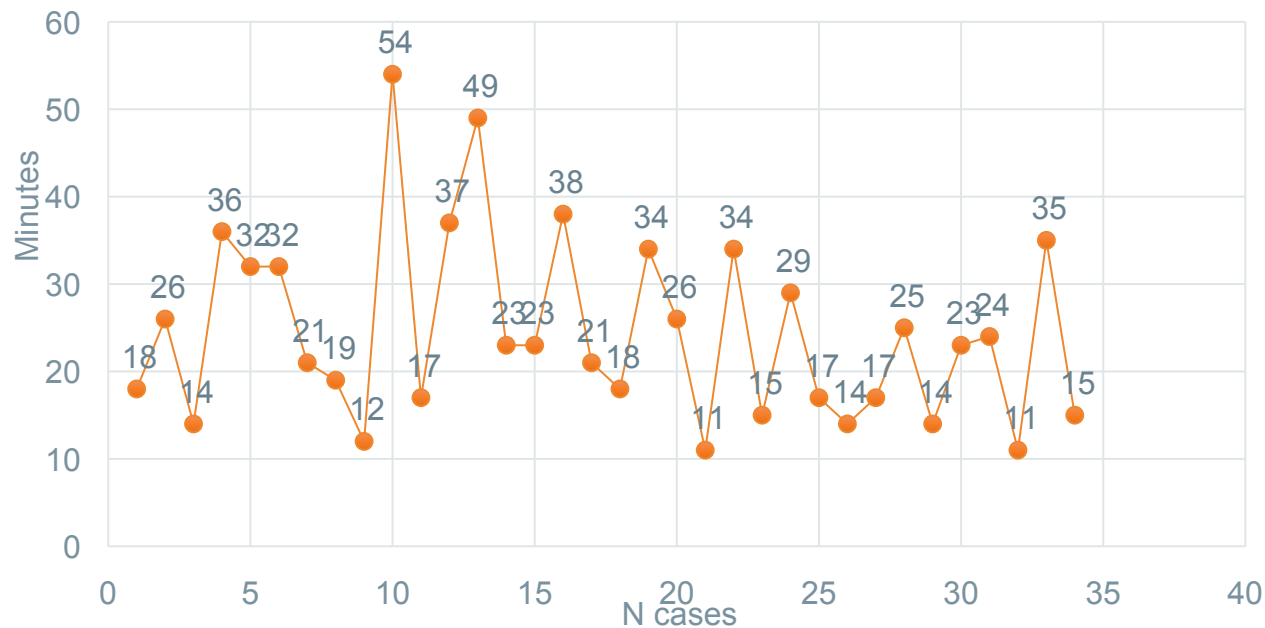
RIPV



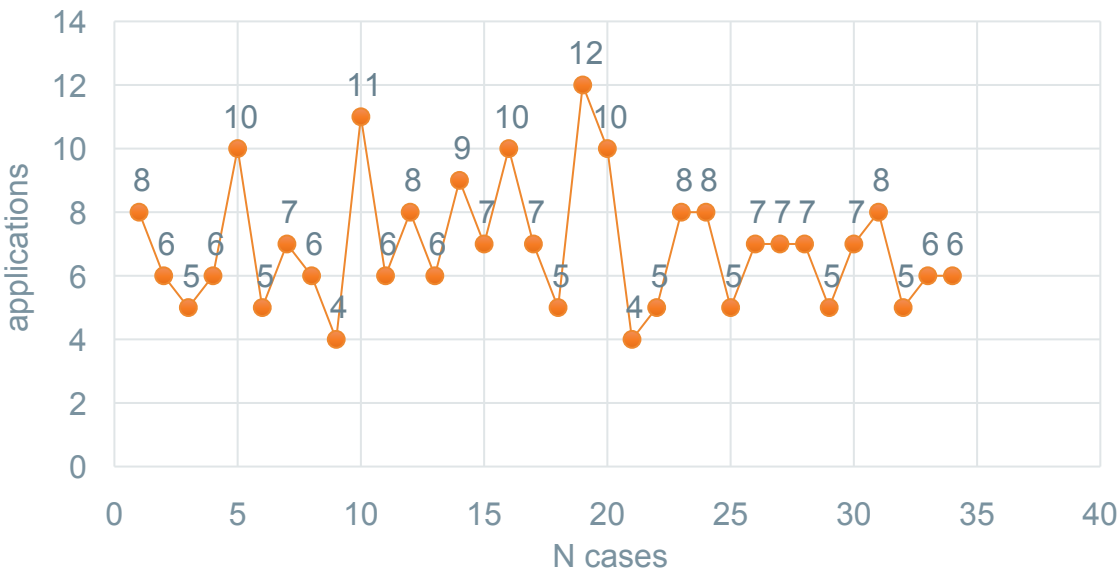
Higher % SSI  
s for PVI

➤ Helios  
➤ Last 2

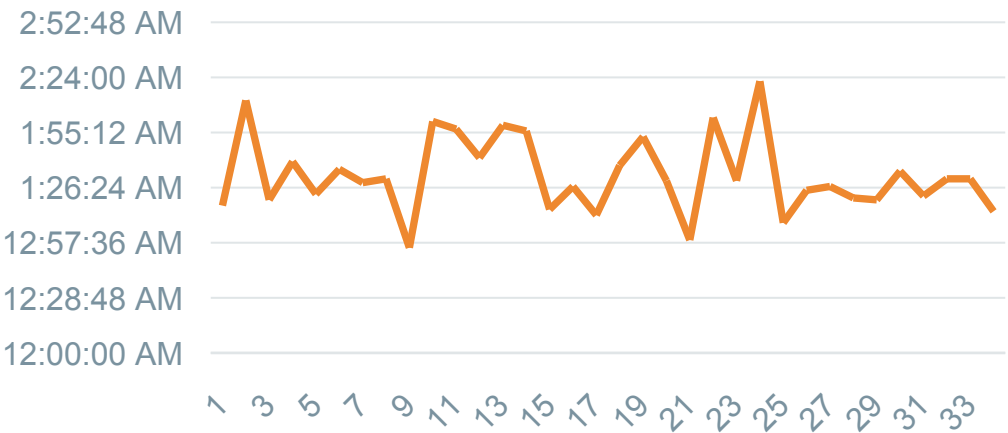
Dwell Time



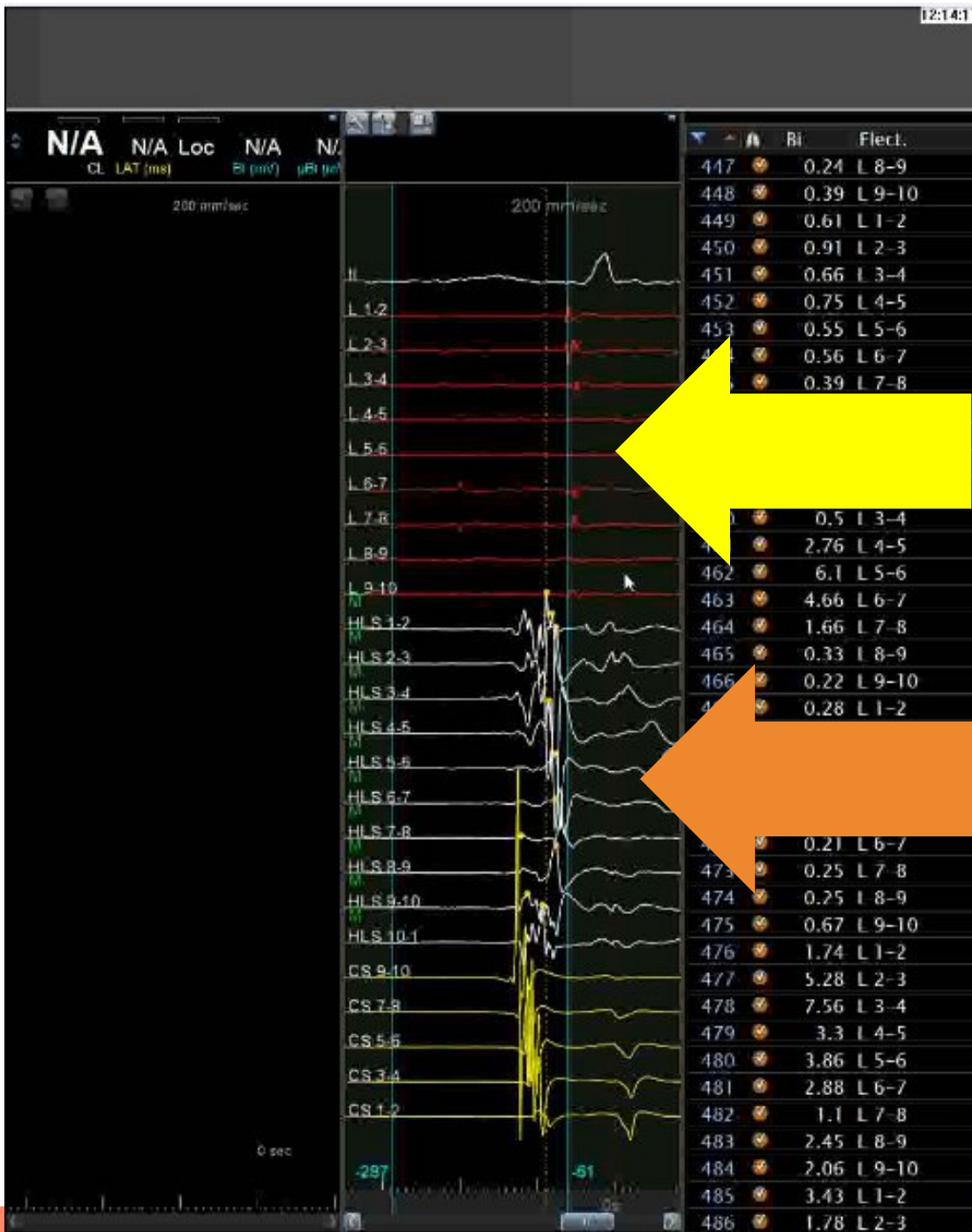
Total number of applications



Skin Length







predictors of success in

ation

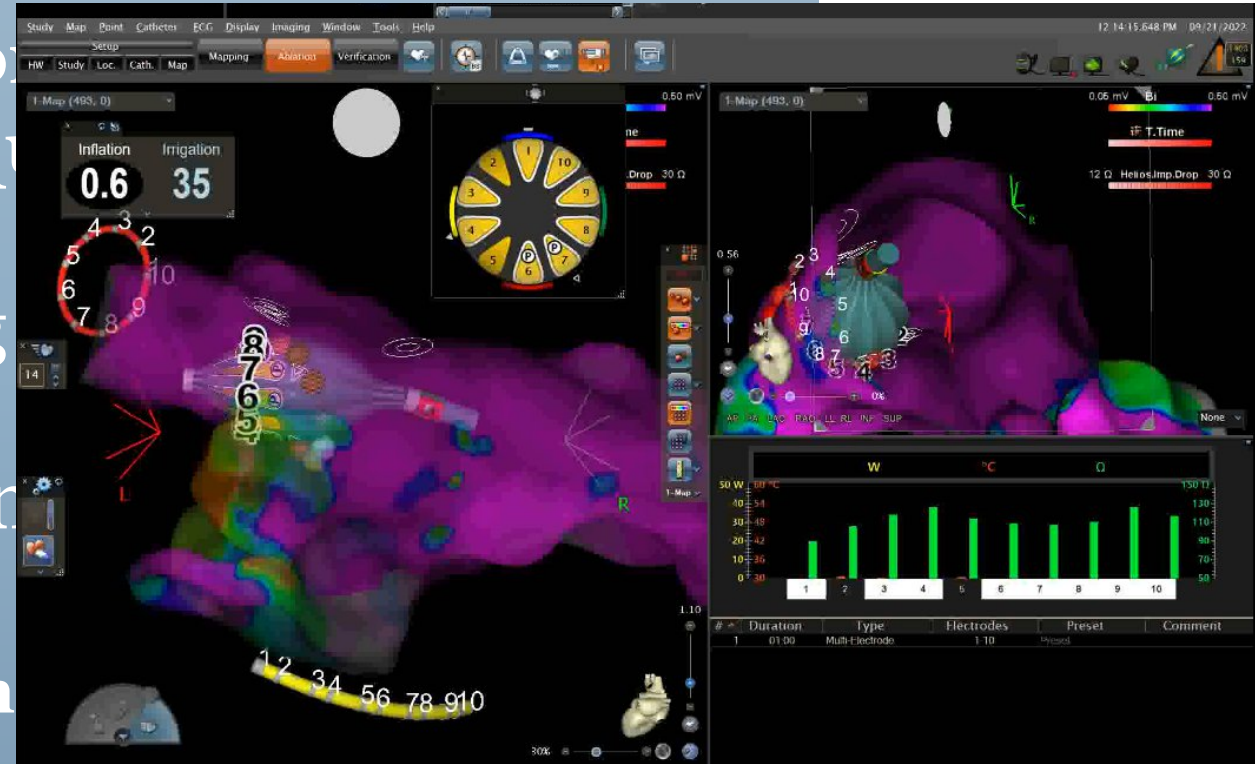
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Dr Gaetano Fassini



# Considerazioni finali

Metodica one shot con elevata efficienza acuta (rapidità e tasso di SSI) ed elevata safety

Possibilità di mappare anche l'area antrale e di estendere localmente la lesione, «doppio mappaggio» PV + antro

Possibilità di effettuare mappaggio atriale ad alta densità

Con l'attuale upgrade, rappresenta un solido competitor nel campo delle metodiche one shot