

# **A Surgical Look at Atrial Fibrillation Treatment**

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**Hashim Hanif**  
**Cardiothoracic Surgeon**  
**MercyOne / Iowa Heart**

# Acknowledgements

**Atricare – for literature and slide share**

# Consequences of Afib

Self-perpetuating, progressive, systemic disease leading to an increased risk of stroke, heart failure, death, dementia and other cardiac complications.

**5x**

**Greater Risk of  
Stroke<sup>1</sup>**

**5x**

**Greater Risk of  
Heart Failure<sup>2</sup>**

**5x**

**Greater Risk  
of Death<sup>1</sup>**

**>3x**

**Greater risk of  
dementia<sup>3</sup>**

**More  
cardiac  
complications<sup>4</sup>**

<sup>1</sup>Odutayo, A. et al. (2016). Atrial fibrillation and risks of cardiovascular disease, renal disease, and death: systematic review and meta-analysis. *BMJ*; 354:i4482

<sup>2</sup>Boriani, G., & Proietti, M. (2017). Atrial fibrillation prevention: an appraisal of current evidence. *Heart*, 104(11):882-7

<sup>3</sup>Bunch TJ et al. *Arrhythmia & Electrophysiology Review* 2019;8(1):8–12

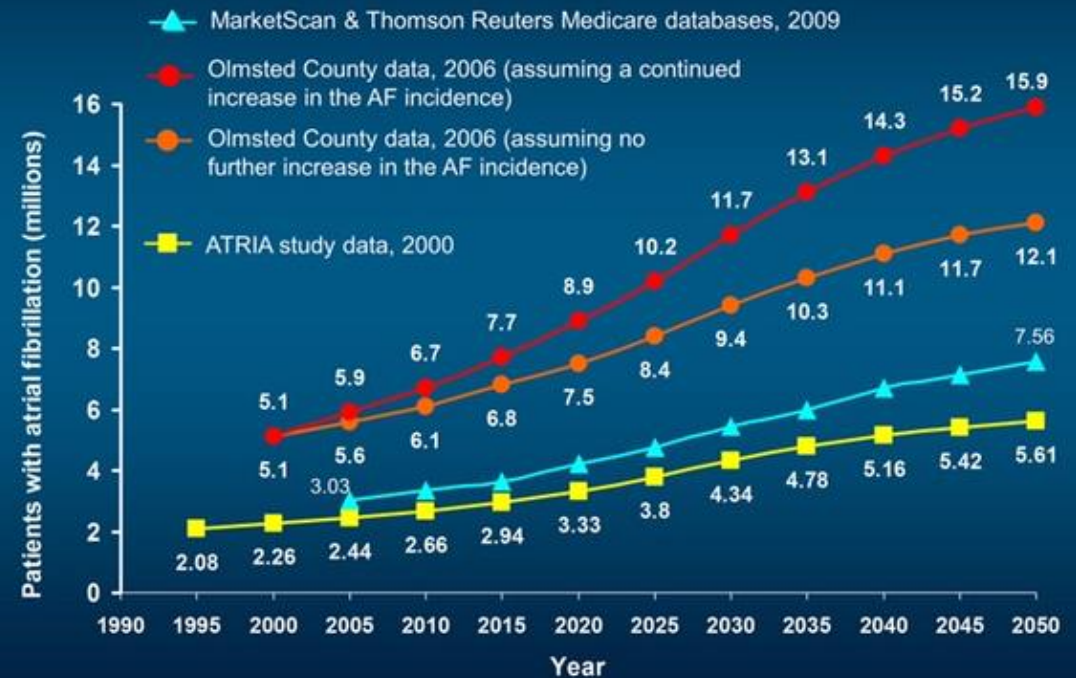
<sup>4</sup>Benjamin, E. J., et al. (2019). Heart disease and stroke statistics—2019 update: a report from the American Heart Association. *Circulation*, 139(10), e56-e528.

## Background: Epidemiology

INCIDENCE of AF will:

- DOUBLE by the year 2050
- 1% of the Population!!!

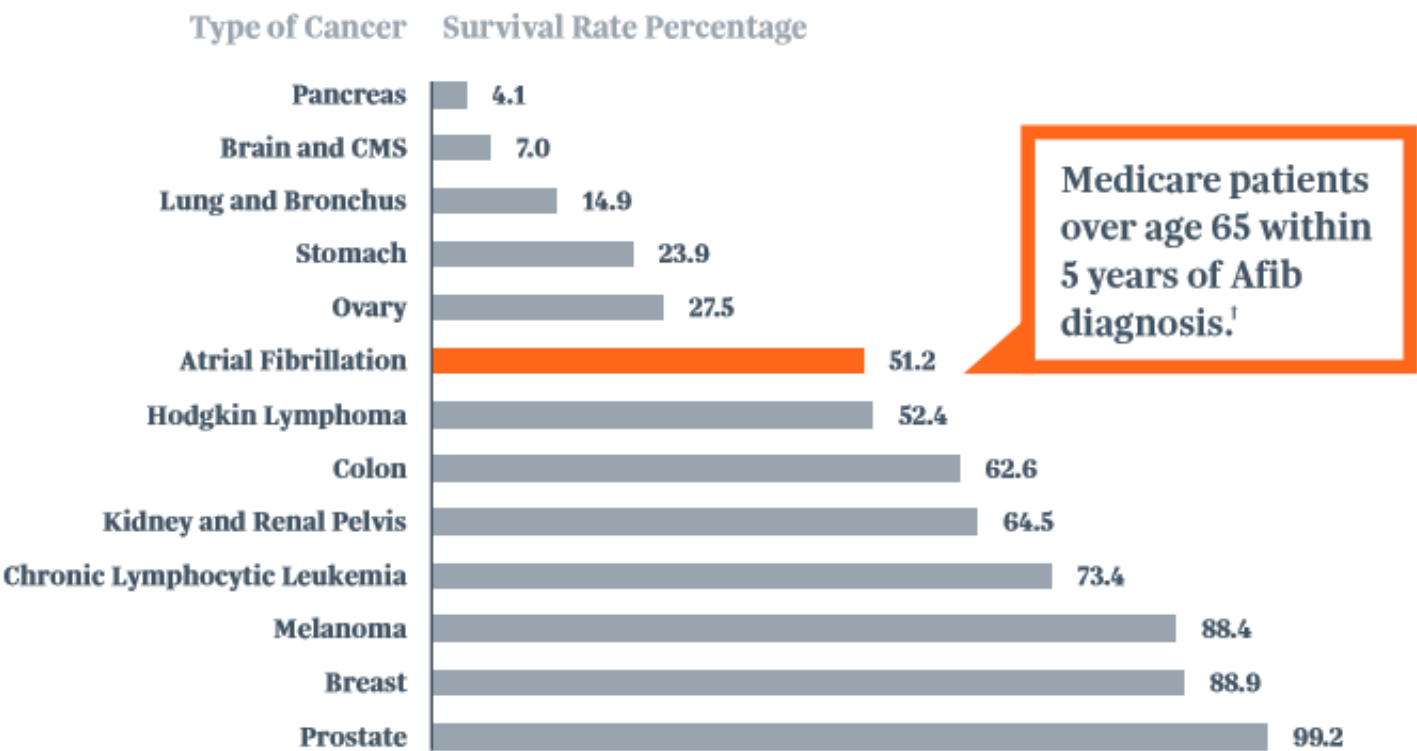
### Projected Number of Patients With AF by 2050



2X

# Severity of Afib is Often Misunderstood

## “Most Feared” Cancer Survival Rates




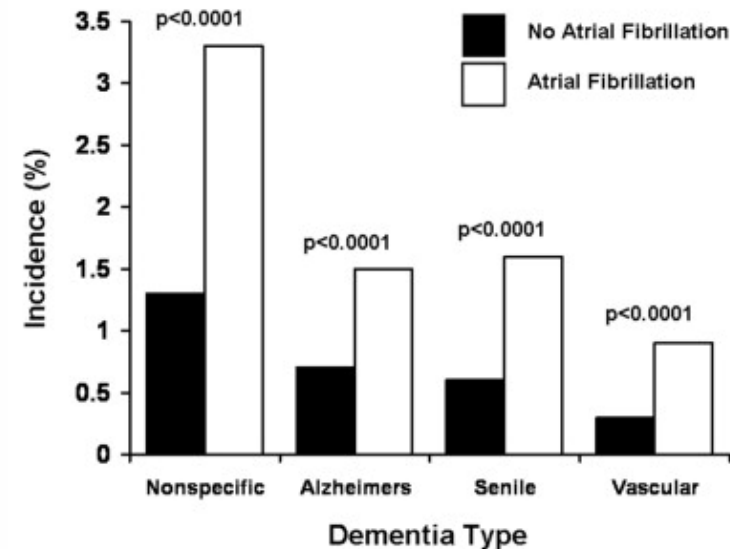
> [Heart Rhythm](#). 2010 Apr;7(4):433-7. doi: 10.1016/j.hrthm.2009.12.004. Epub 2009 Dec 11.

## Atrial fibrillation is independently associated with senile, vascular, and Alzheimer's dementia

T Jared Bunch <sup>1</sup>, J Peter Weiss, Brian G Crandall, Heidi T May, Tami L Bair, Jeffrey S Osborn, Jeffrey L Anderson, Joseph B Muhlestein, Benjamin D Horne, Donald L Lappe, John D Day

Multivariate Odds Ratios for Association of AF based on Age and Dementia Type

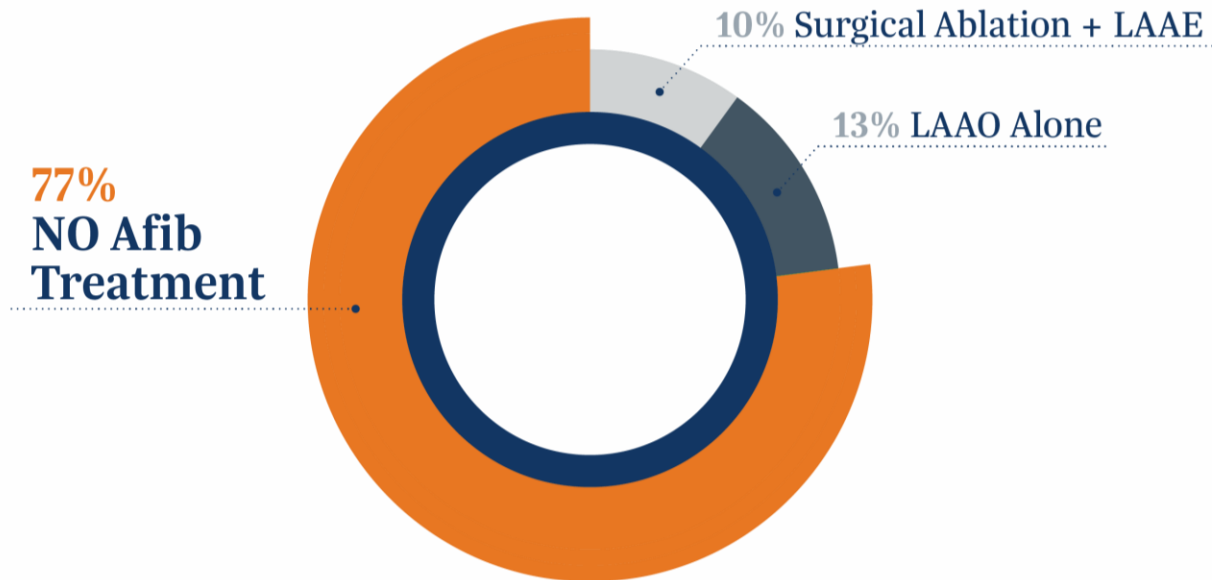
Dementia	Overall	≤70 	70-79	80-89	≥90
Vascular	1.73 p=0.001	2.22 p=0.004	1.68 p=0.02	1.31 p=0.45	-----
Senile	1.39 p=0.005	3.34 p<0.0001	1.60 p<0.0001	0.93 p=0.004	0.54 p=0.41
Alzheimers	1.06 p=0.59	2.30 p=0.001	1.07 p=0.68	0.81 p=0.29	0.81 p=0.37
Nonspecific	1.44 p<0.0001	2.87 p<0.0001	1.49 p=0.001	0.96 p=0.77	0.60 p=0.44



Younger patients who had AF were at higher risk for all types of dementia

# How Many Patients Go Undertreated?

From 2018 to 2020, 103,382 Medicare beneficiaries with Afib  
undergoing cardiac surgery:



# Risks of Untreated Afib

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## CABG

- Greater than 20% increased mortality at 10 years<sup>1</sup>
- Increased post-op morbidity (twice the stroke risk)

## AVR

- Worse late survival (RR=1.5)
- More post-op stroke (16%vs.5%) and CHF (25%vs.10%)

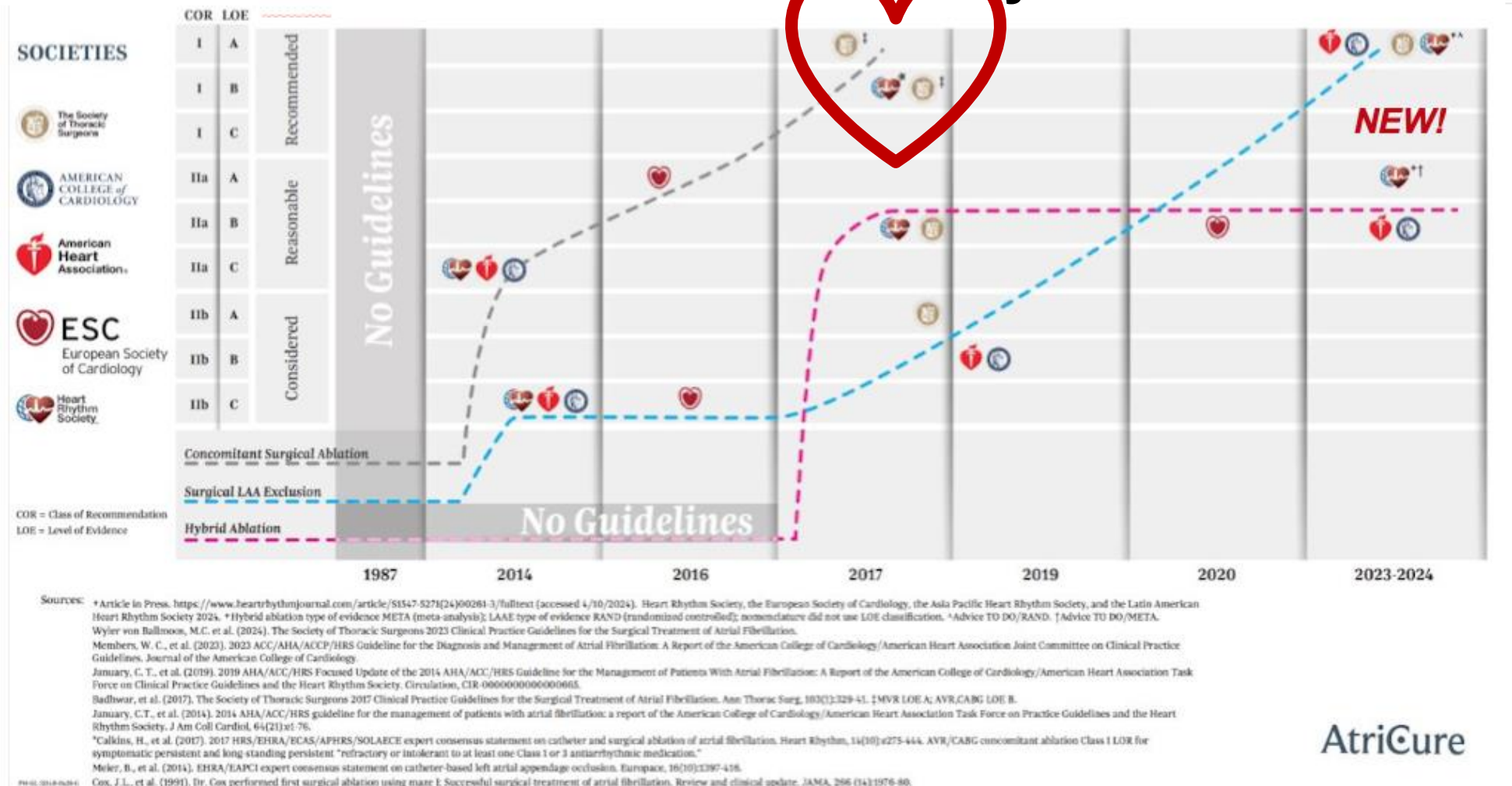
## MVR

- 18% difference in survival at 10 years
- 32% increase in late cardiac events and stroke

<sup>1</sup>J Thorac Cardiovasc Surg 2018;155:159-70



# Current Guidelines For Concomitant & Hybrid and LAA



Surgical ablation for AF is a **Class IA** recommendation

# Guideline Supported: STS Guidelines



## Updates from 2017 Guidelines

- **Left atrial appendage: Class IA, Level A**
- Low-Intermediate Risk: SAVR+SA: Class IIA, Level B
- Stand-Alone LAAO: Class IIB, Level B

# Concomitant Treatment Strategies

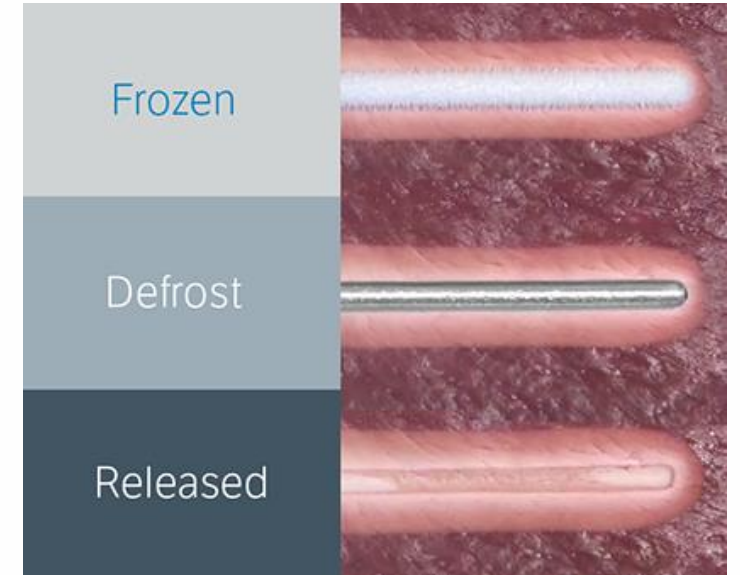
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# Fundamentals of Surgical Ablation



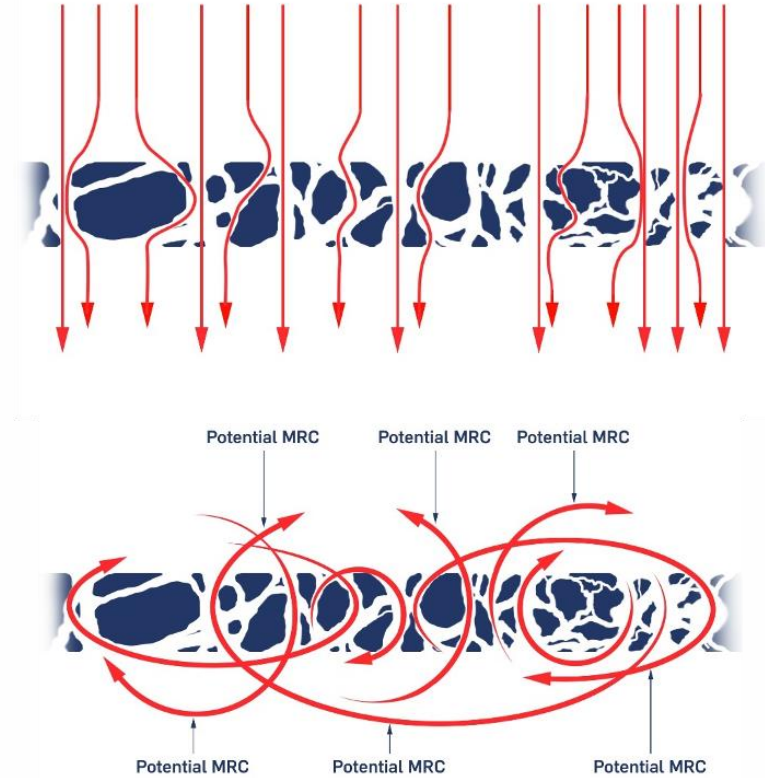
## Available options:

- AtriCure RF Clamp
- AtriCure Cryo probe



# Fundamentals of Surgical Ablation

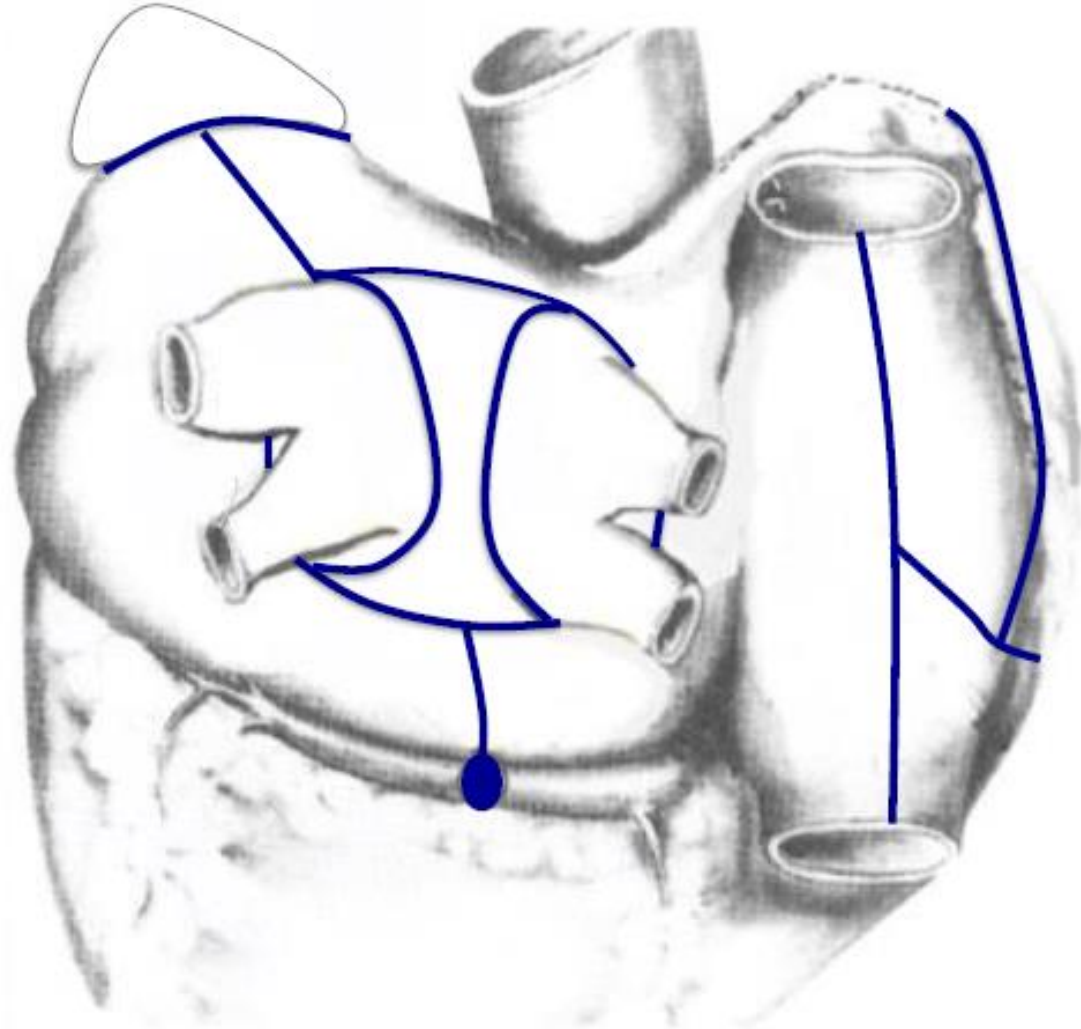
1. Transmural (full thickness)
2. Anchored in non-conductive tissue
  1. Right or Left Atriotomy
  2. Transmural Ablation (e.g., PVI)
  3. SVC
  4. IVC
  5. Tricuspid annulus
  6. Mitral annulus



EVERY LESION HAS TO BE PERFECT

# Building the Cox-Maze IV

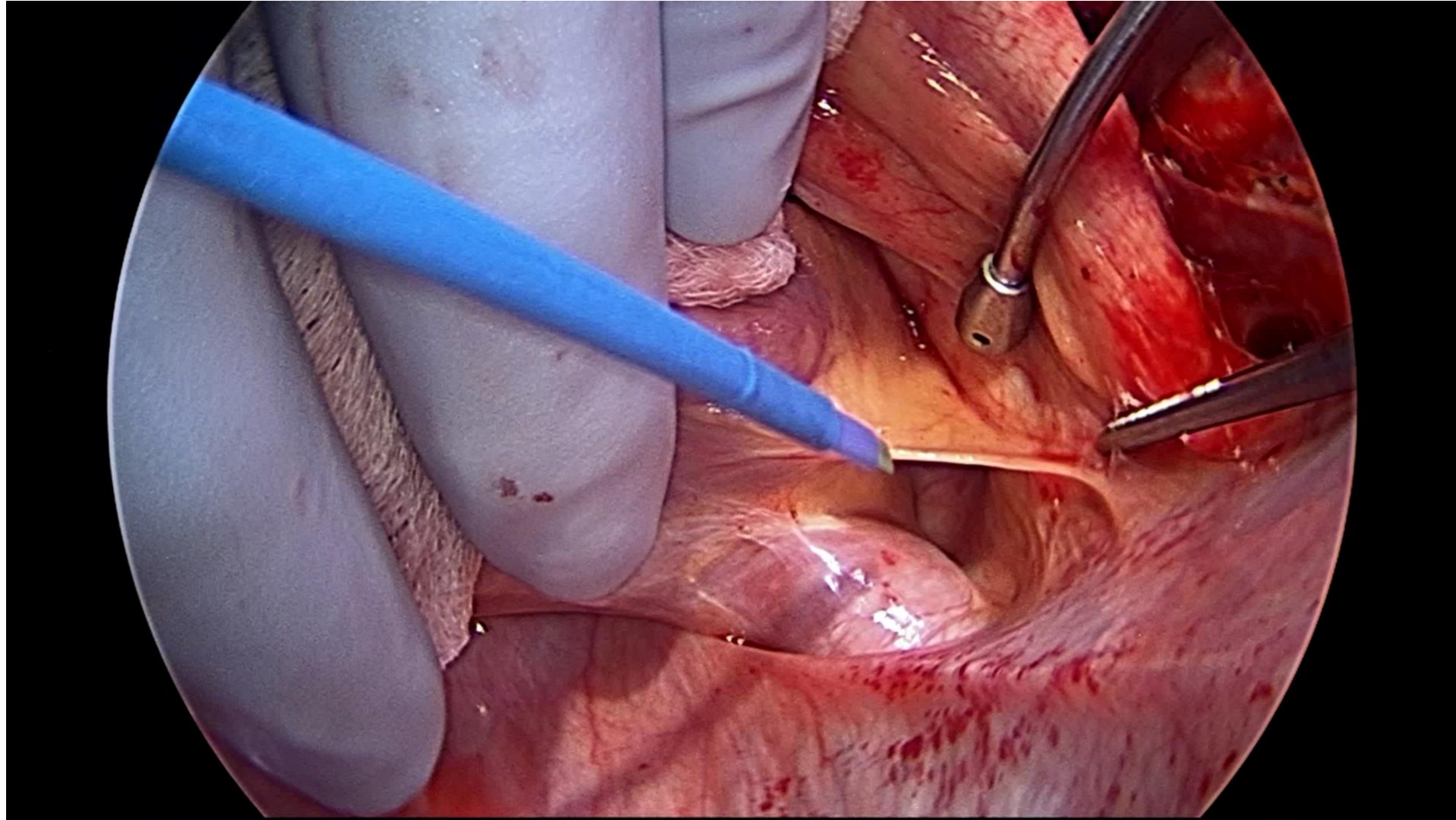
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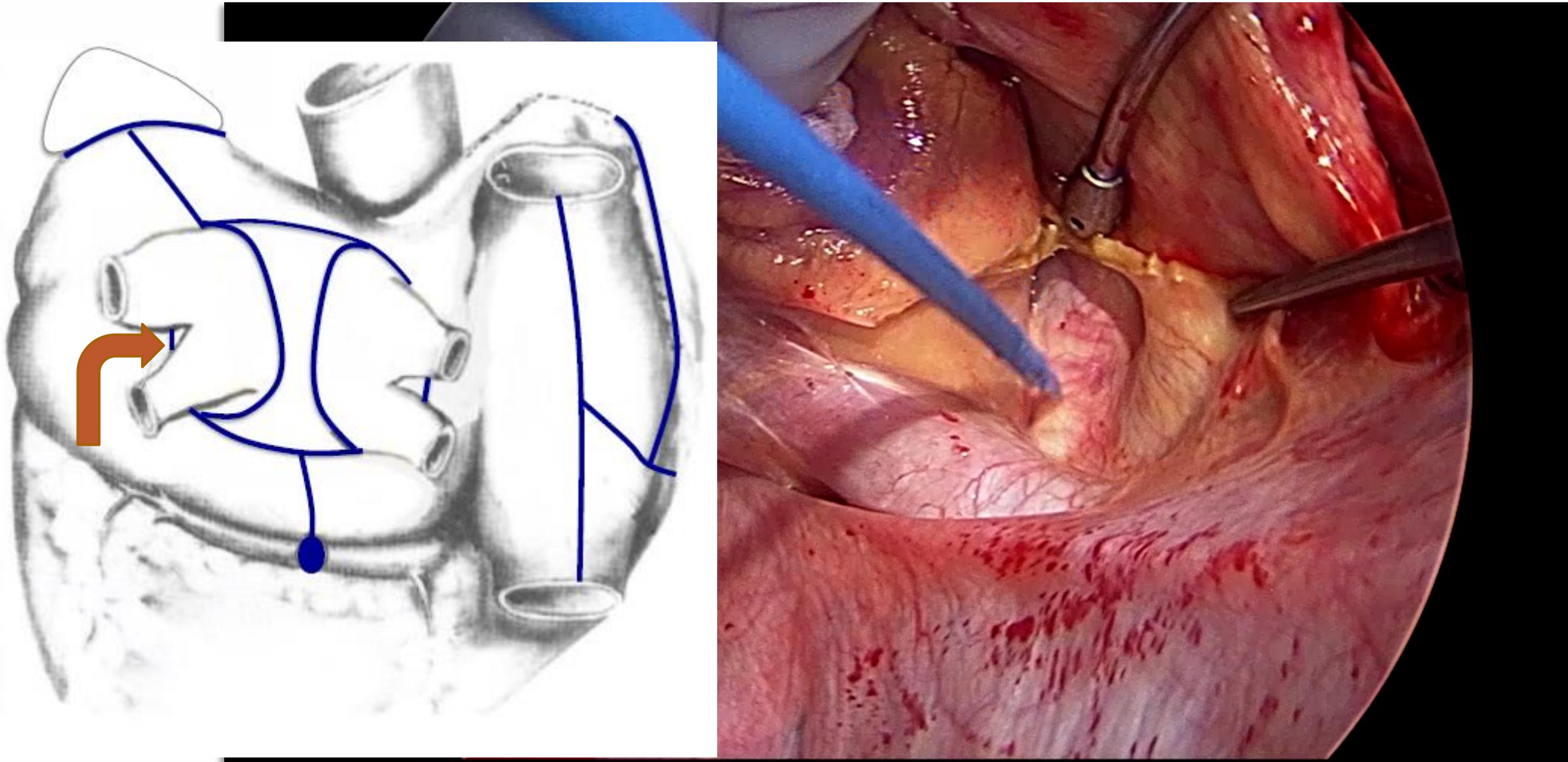


# Ligament of Marshall

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# Left Sided PVI



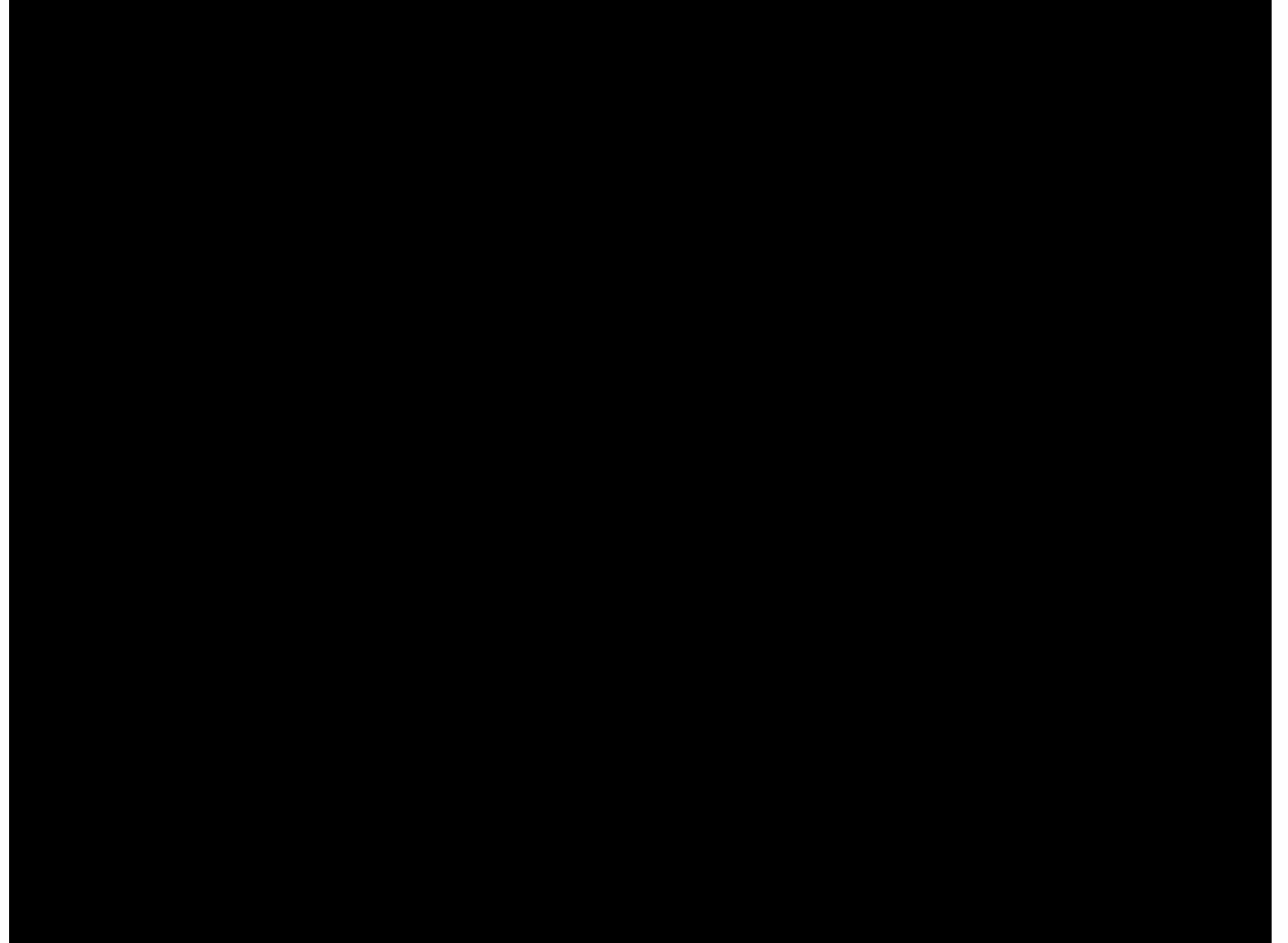
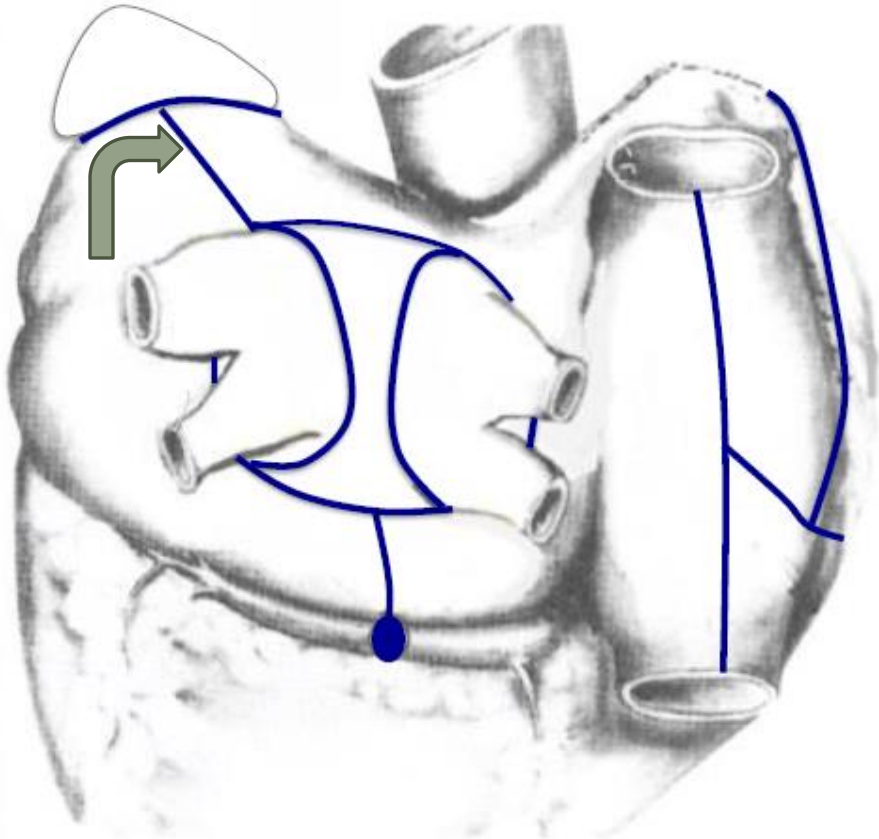


# Construction of Left Atrial Ablation

## Coumadin Ridge & LAAE

Step 1. Incise the tip of the LAA

Step 2. Ablation from the open tip of LAA  
across the Left PVI

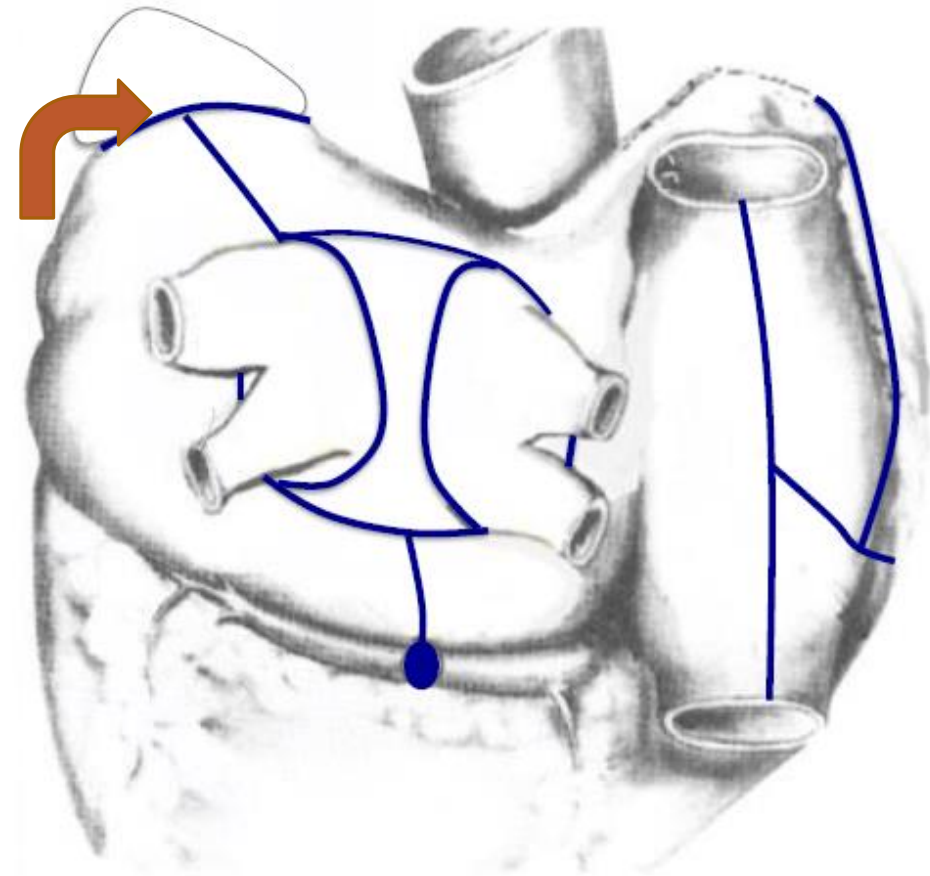
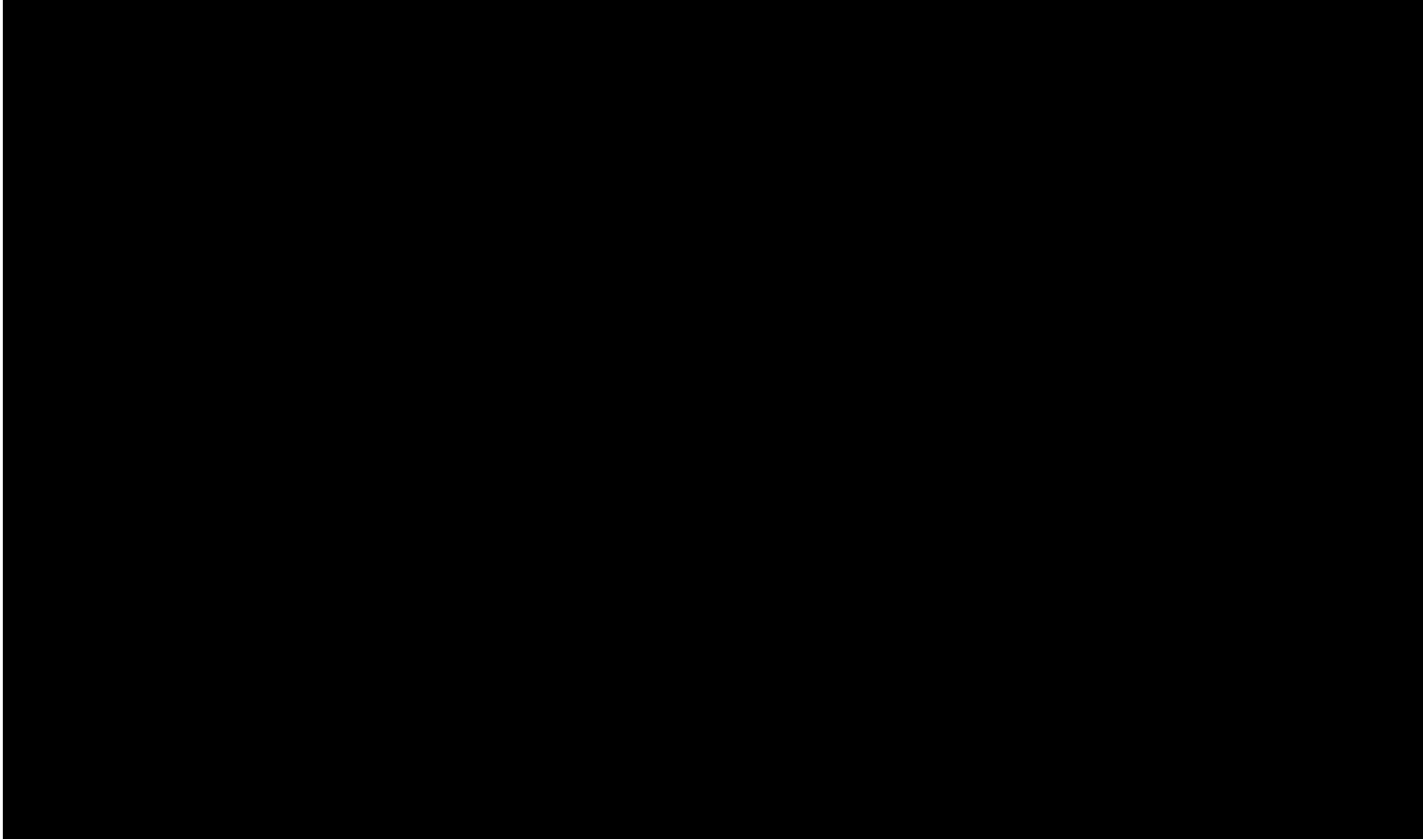


Pictures courtesy of Dr. Marc Gerdisch

AtriCure

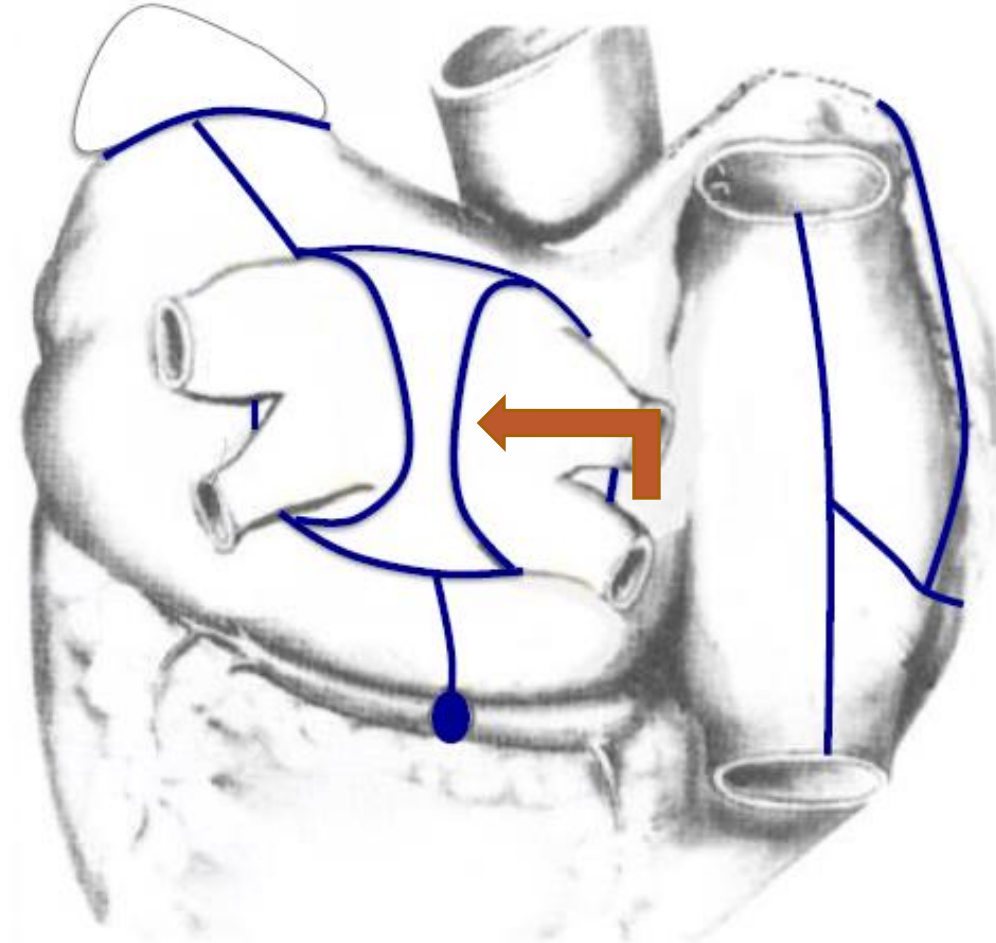
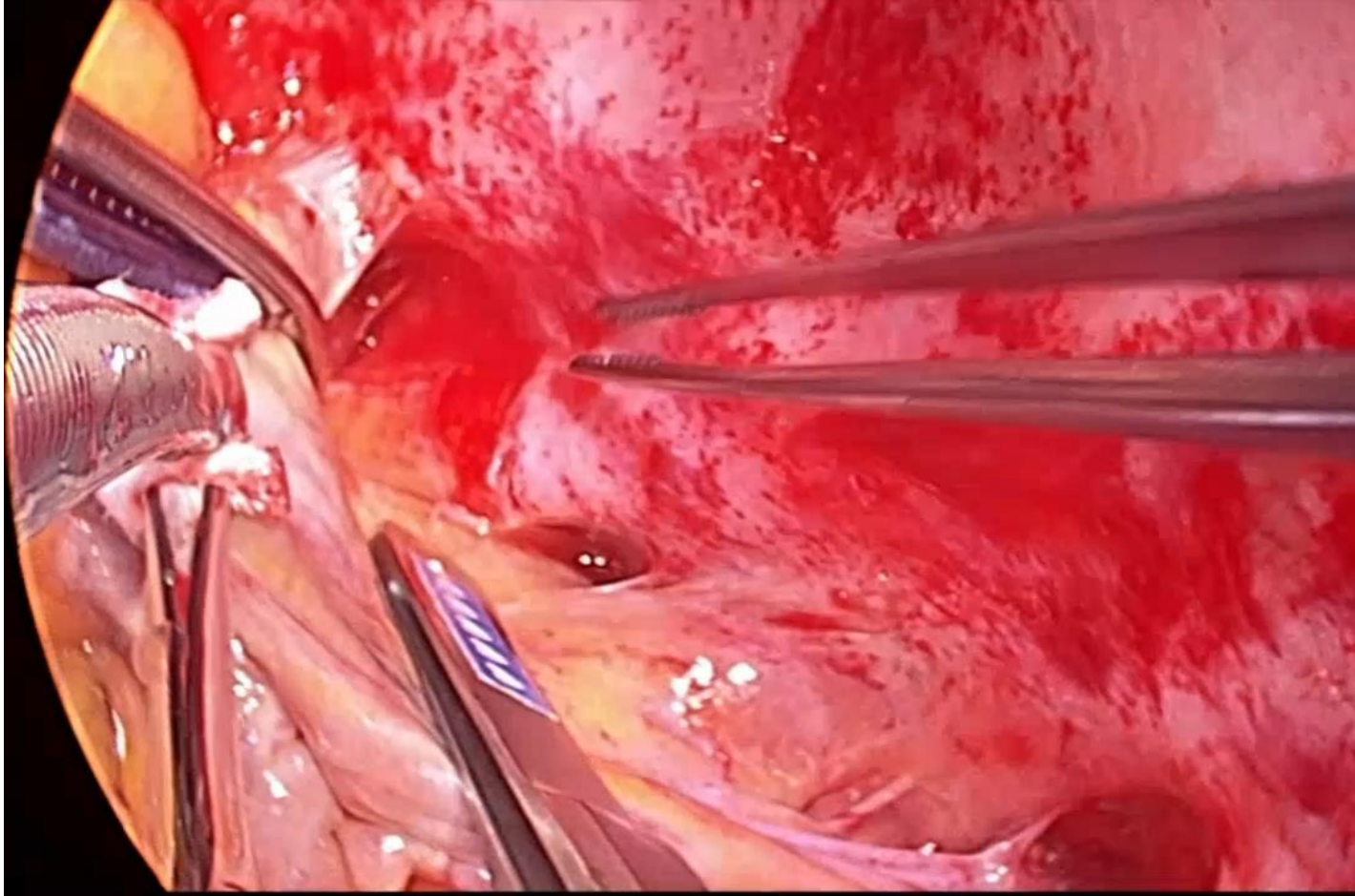
# LAAO AtriClip Technique Video

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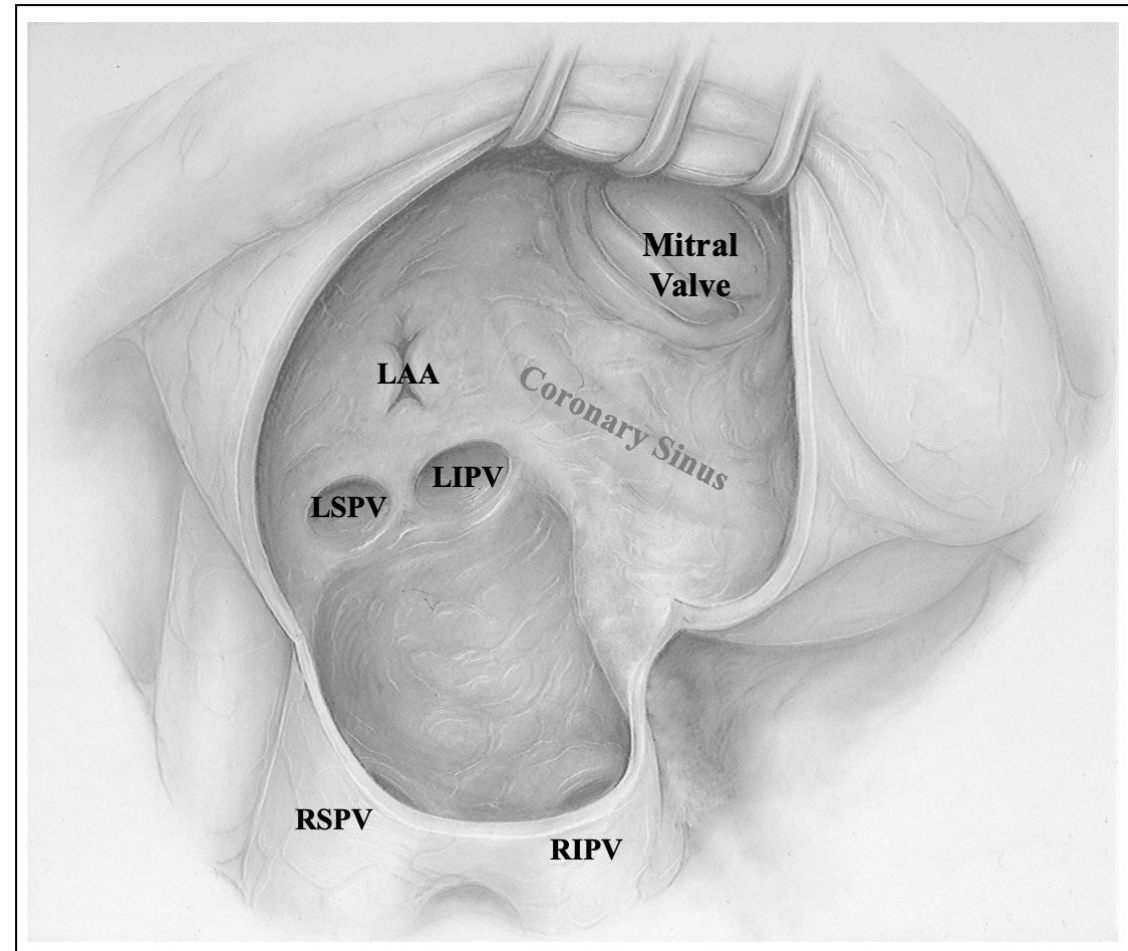


# Next Up - The Right Pulmonary Veins

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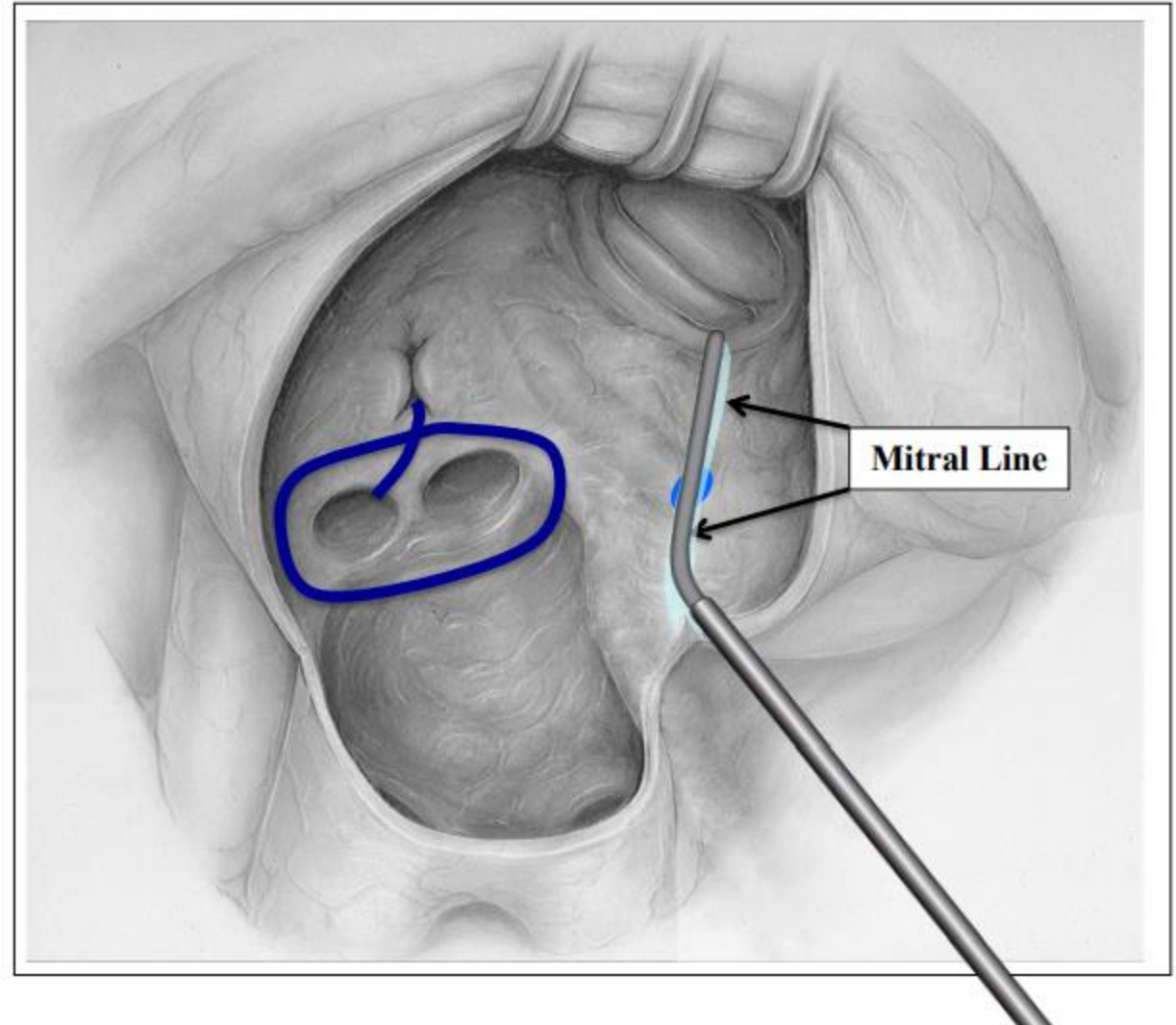


# Left Atrial Atriotomy

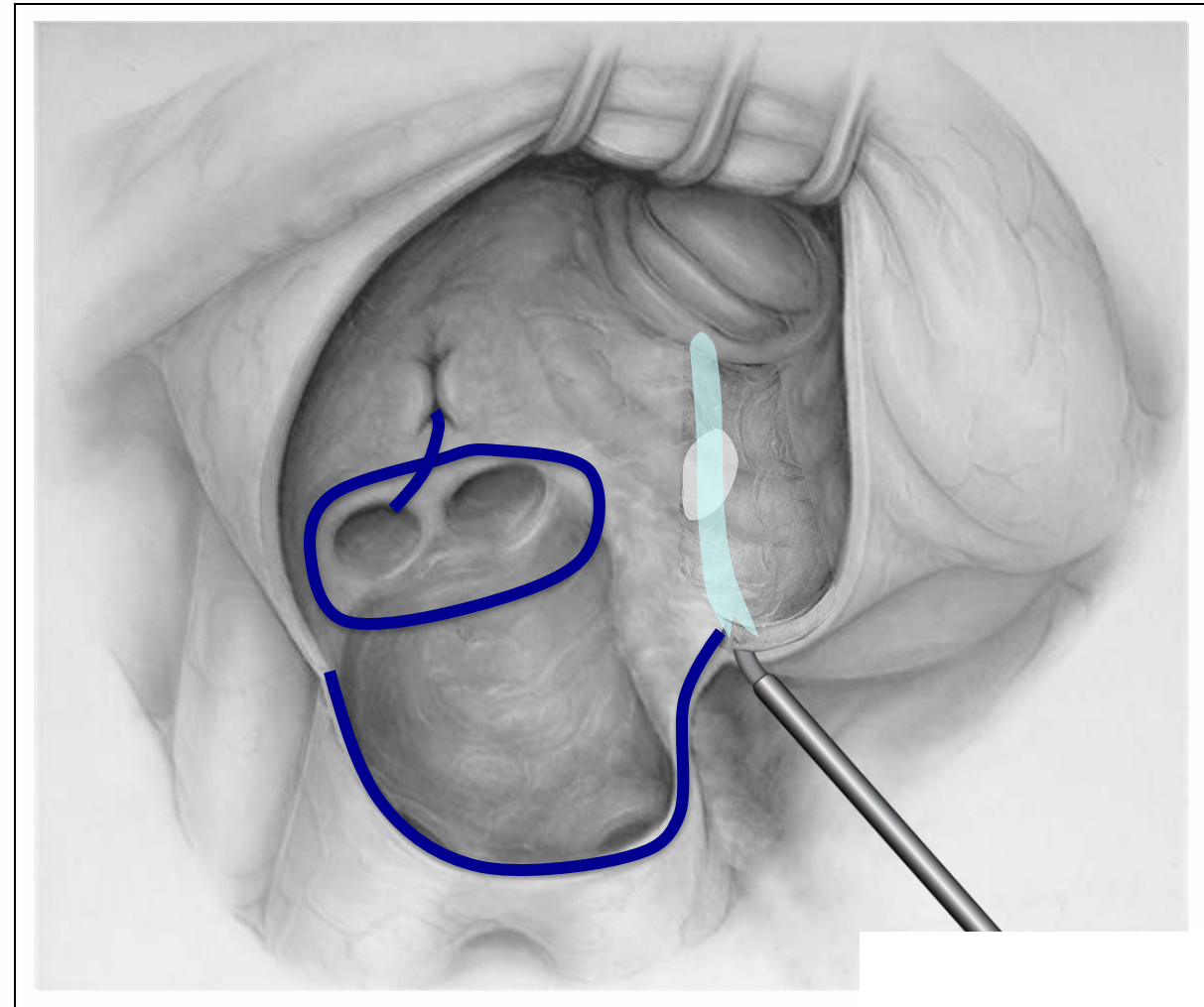




# Mitral Line

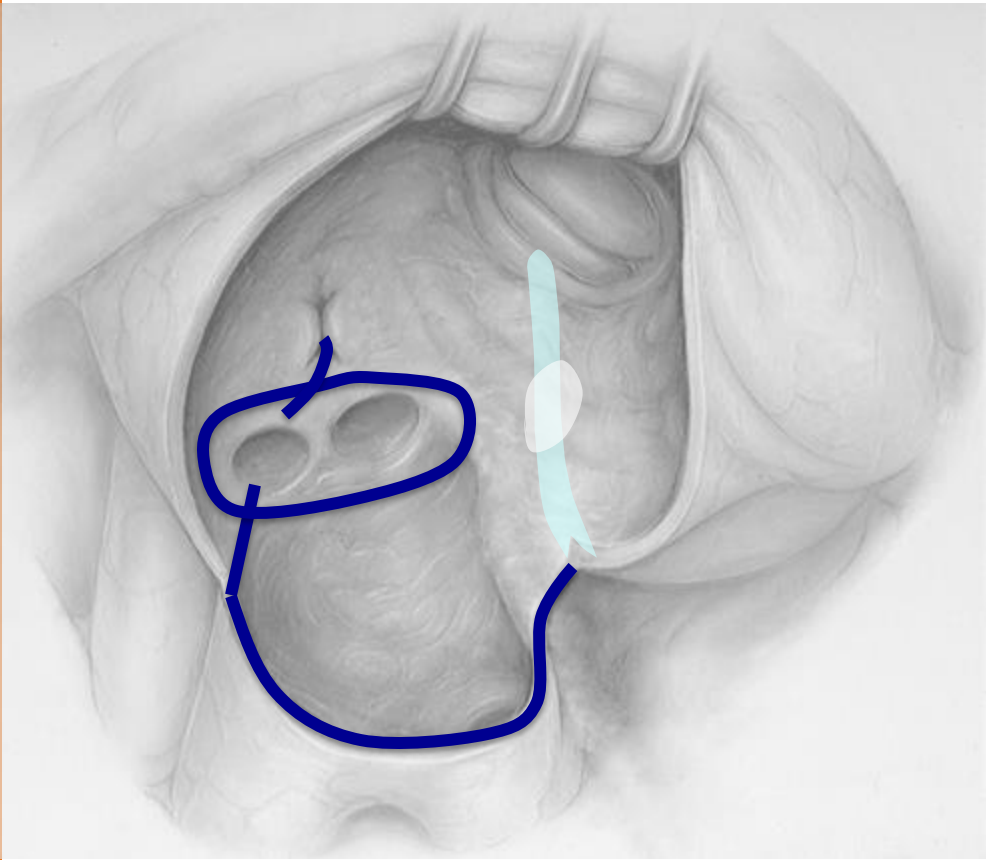


# Coronary Sinus Lesion



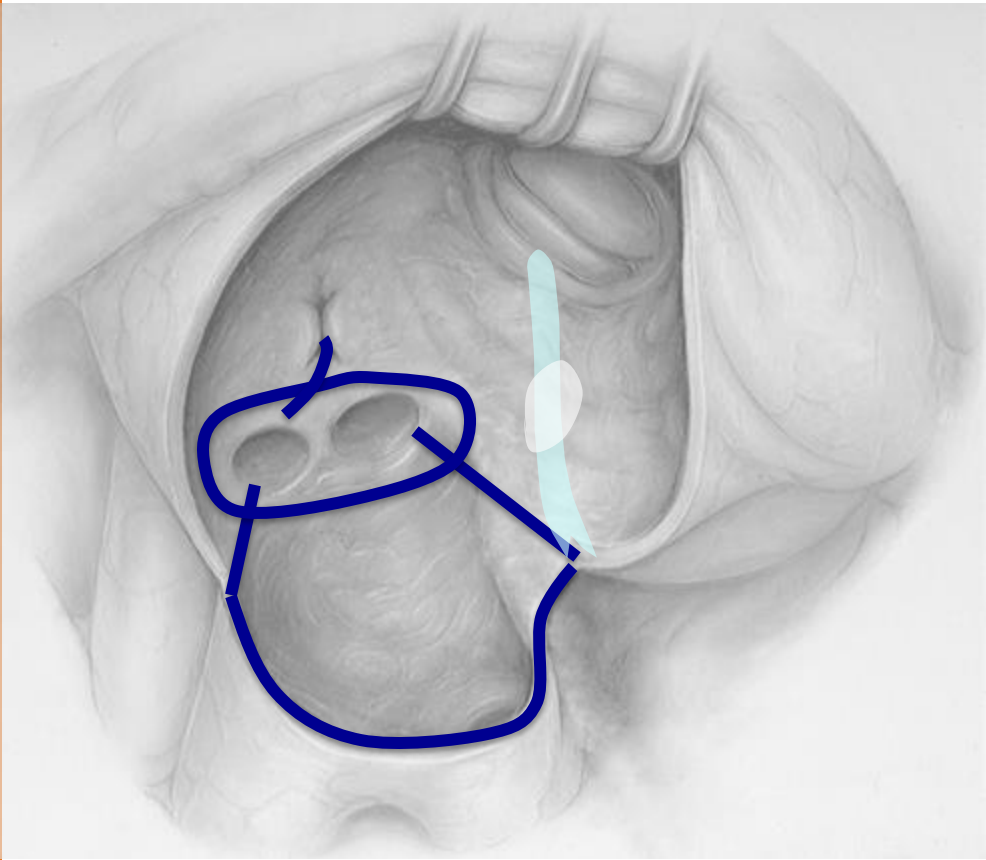
# Roof Lesion

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# Floor Lesion

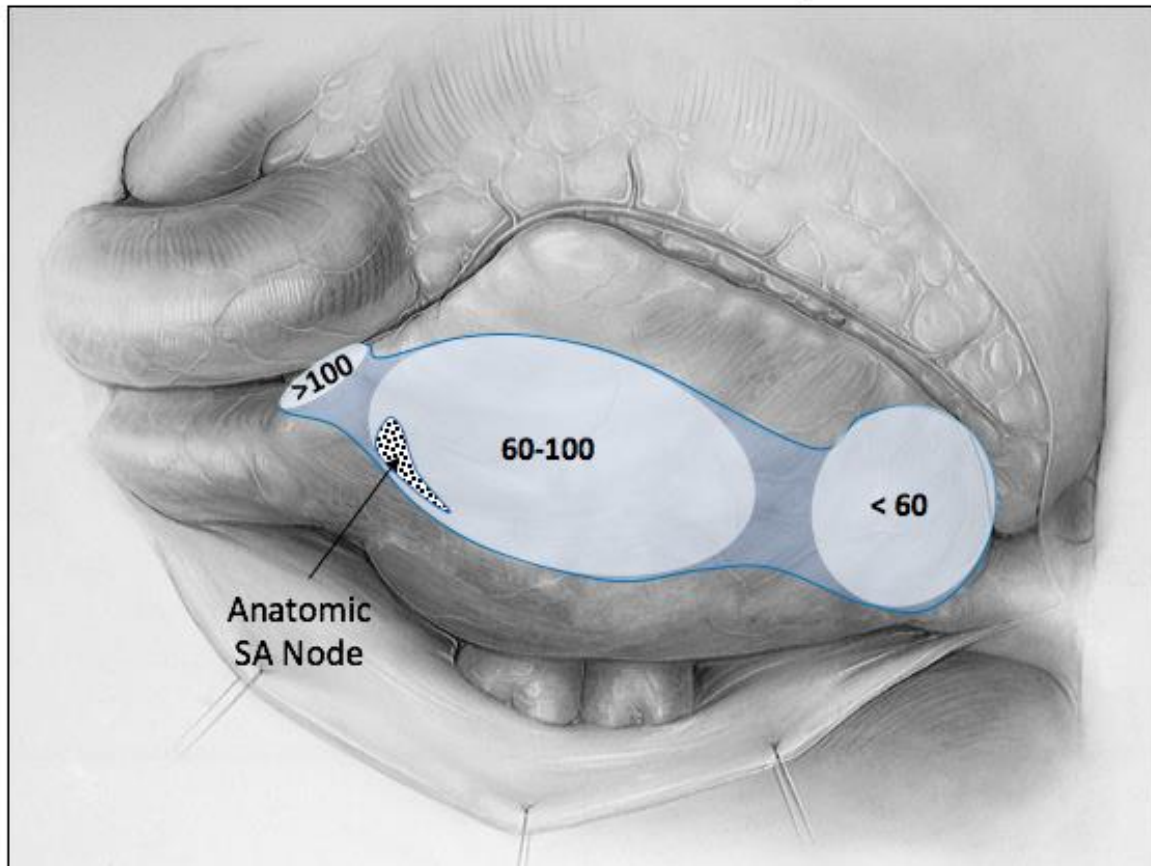
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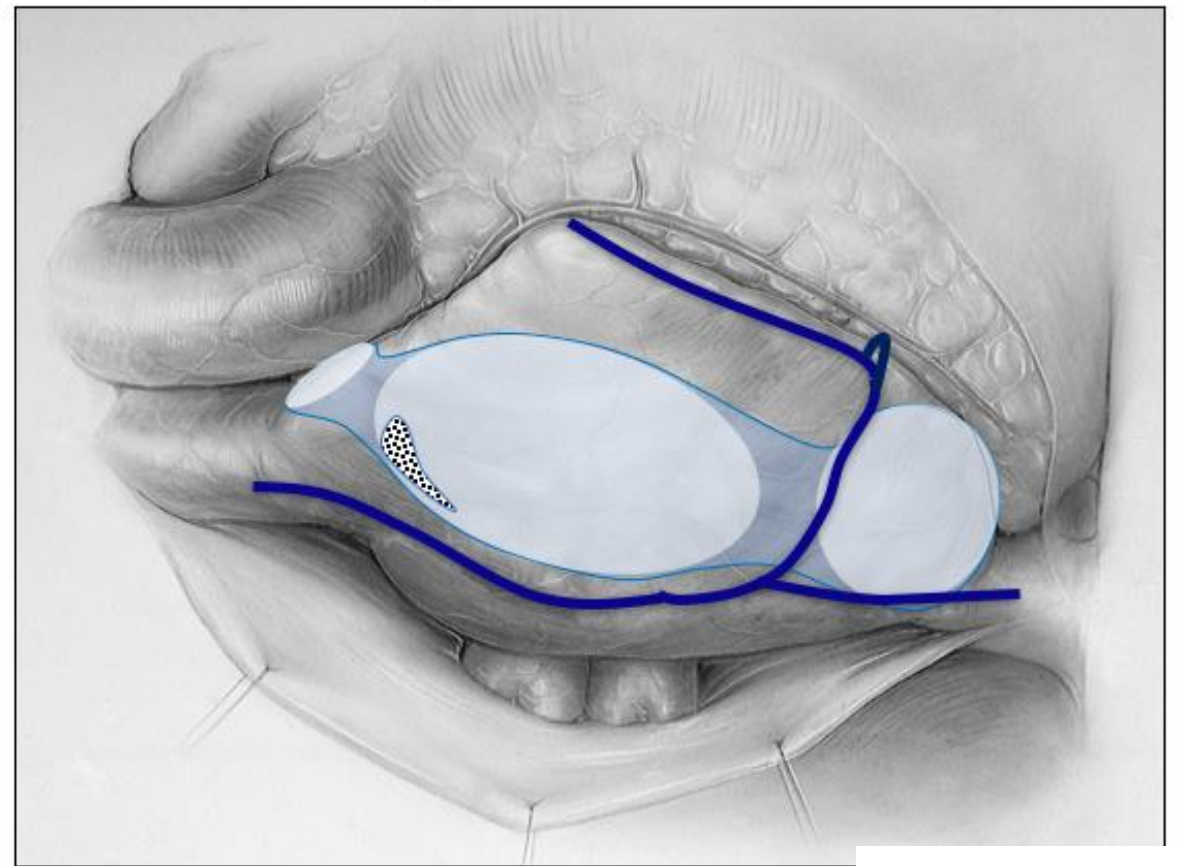


# Right Atriotomy Incision Planning

Atrial Pacemaker Complex

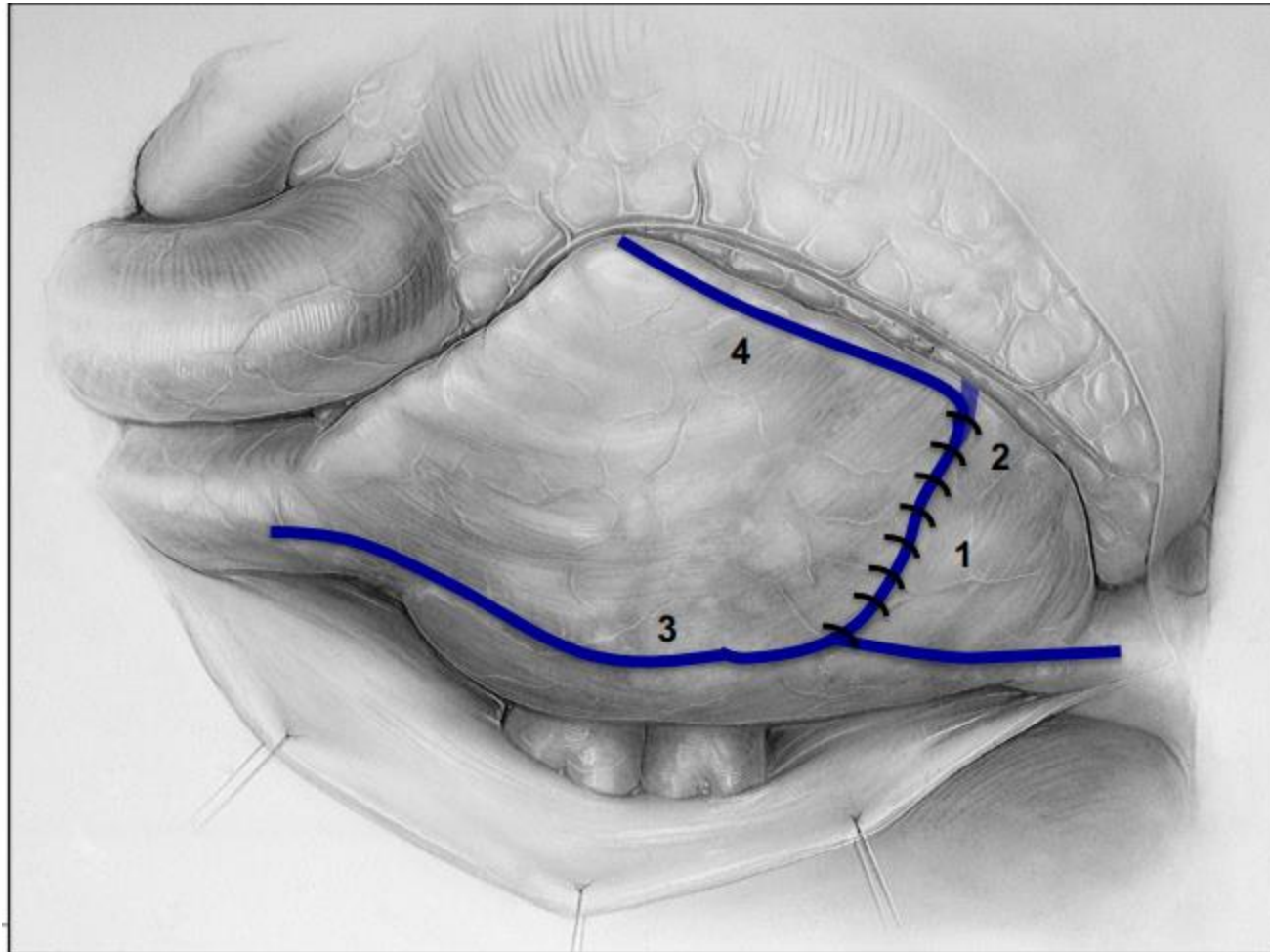


Right Atrial Lesions



# Completed Right Atrial Lesions

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## Ablations & Sequence

### 1. Right Atrial Free Wall

- Atriotomy

### 2. Tricuspid Annulus – Isthmus

- Cryotherapy

### 3. Inter-caval (SVC-IVC)

- RF
- Cryotherapy

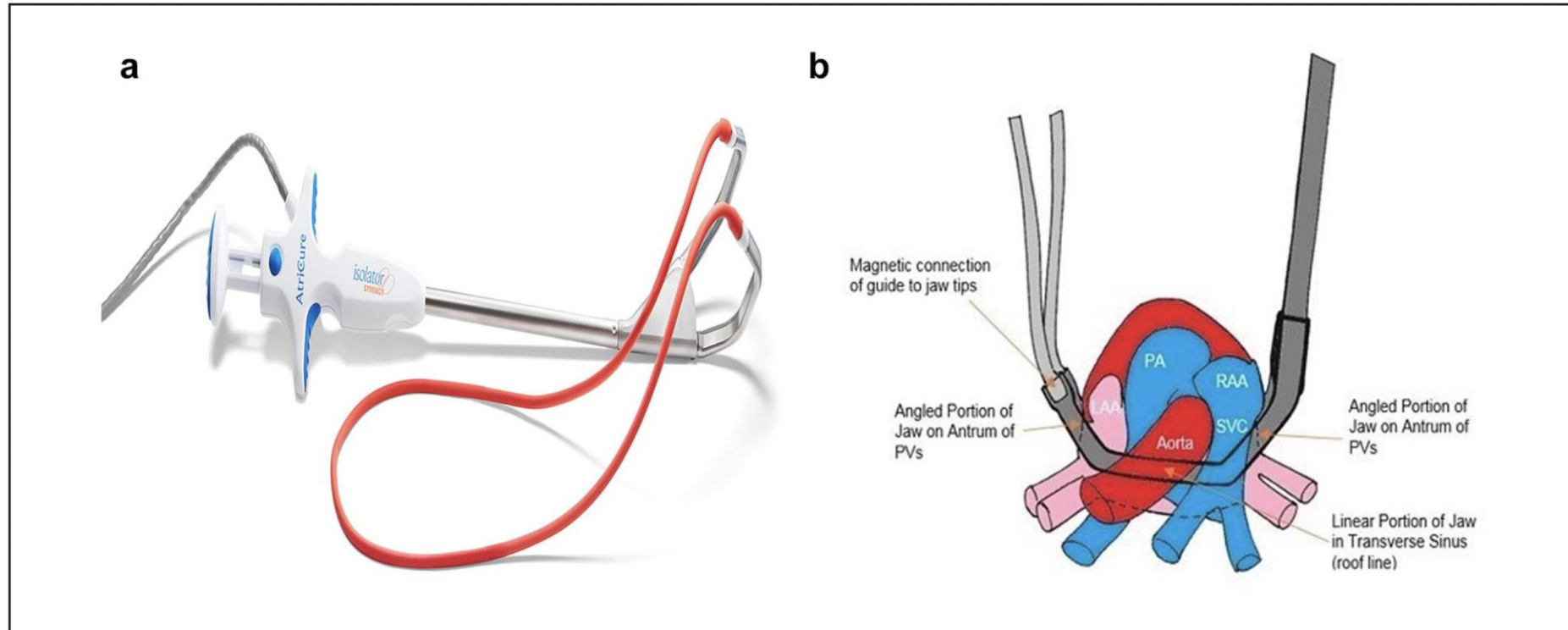
### 4. Right Atrial Appendage

- RF
- Cryotherapy

# Alternative Approaches to Ablation

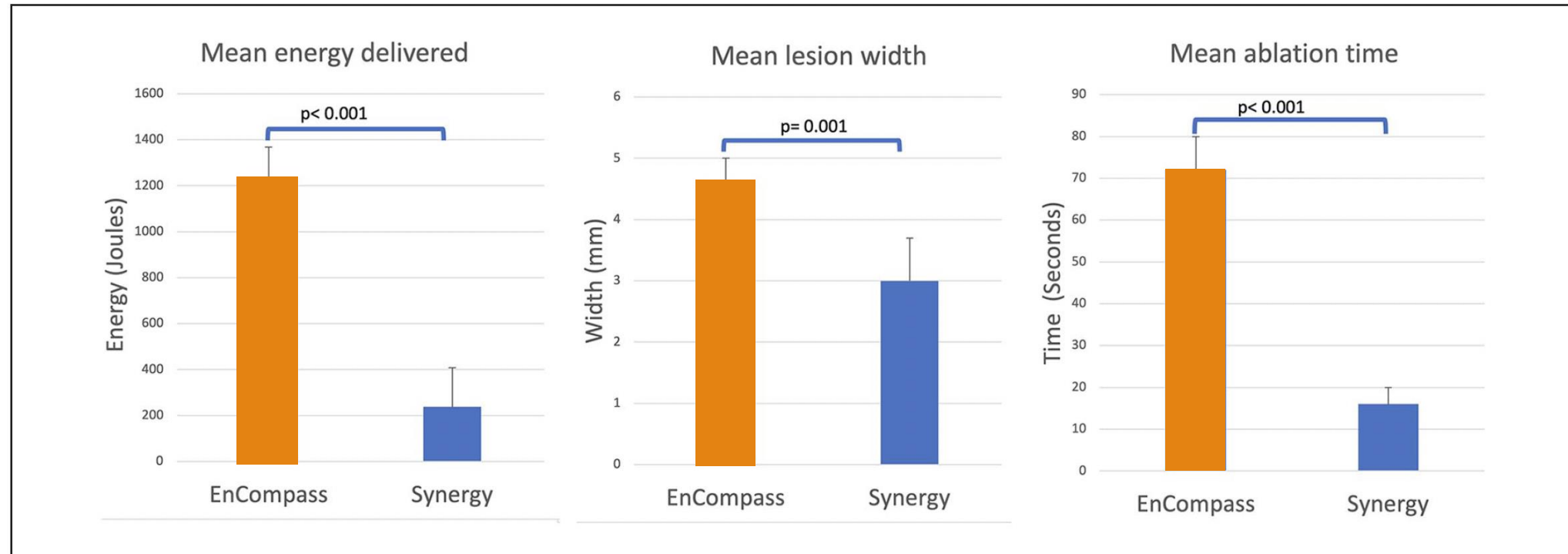
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# Fundamentals of Surgical Ablation



**Fig. 1.** (a) The EnCompass™ device (AtriCure, Inc., Mason, OH, USA) is a nonirrigated dual-electrode bipolar radiofrequency clamp. The magnetized red rubber guide system is used to assist in the placement of the clamp. (b) The EnCompass™ clamp creates a box lesion that isolates the entire left atrial posterior wall in a single application.

# Fundamentals of Surgical Ablation

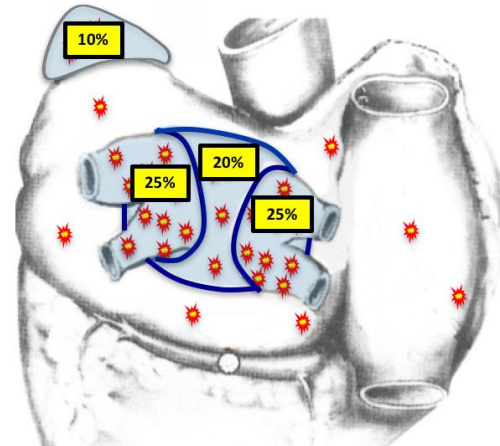


**Fig. 4.** Comparison of the mean energy delivery, lesion width, and ablation time between the EnCompass™ and Synergy™ bipolar radiofrequency clamps.

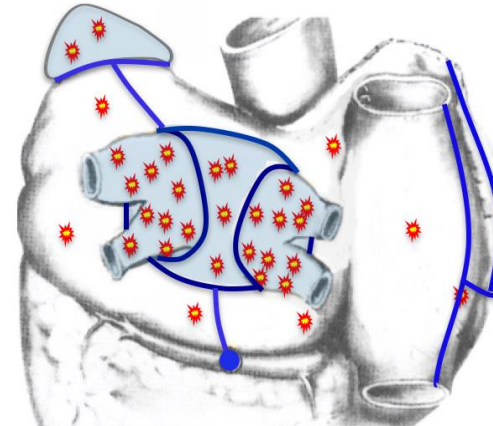
NO change in cannulation, NO posterior atrial dissection, NO additional cross-clamp time

# CABG and/or AVR Patients with PAF

## Viability Options



Box Lesion + LAAO



Maze Procedure

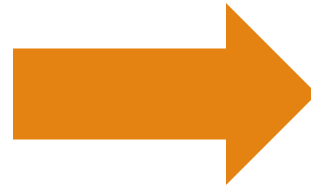
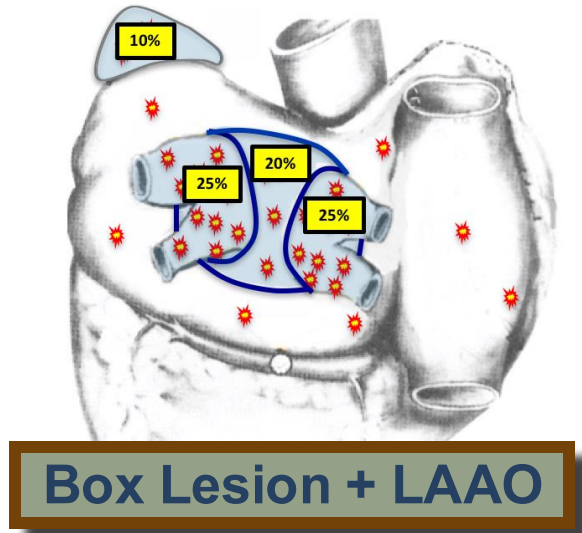
- **Surgical Options:**

- Box Lesion + LAAO - 80% less PAF + Stroke Protection
- Maze Procedure - > 90% less PAF + Stroke Protection



# CABG and/or AVR Patients with PAF

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LAAO with AtriClip



# CABG and/or AVR Patients with PAF

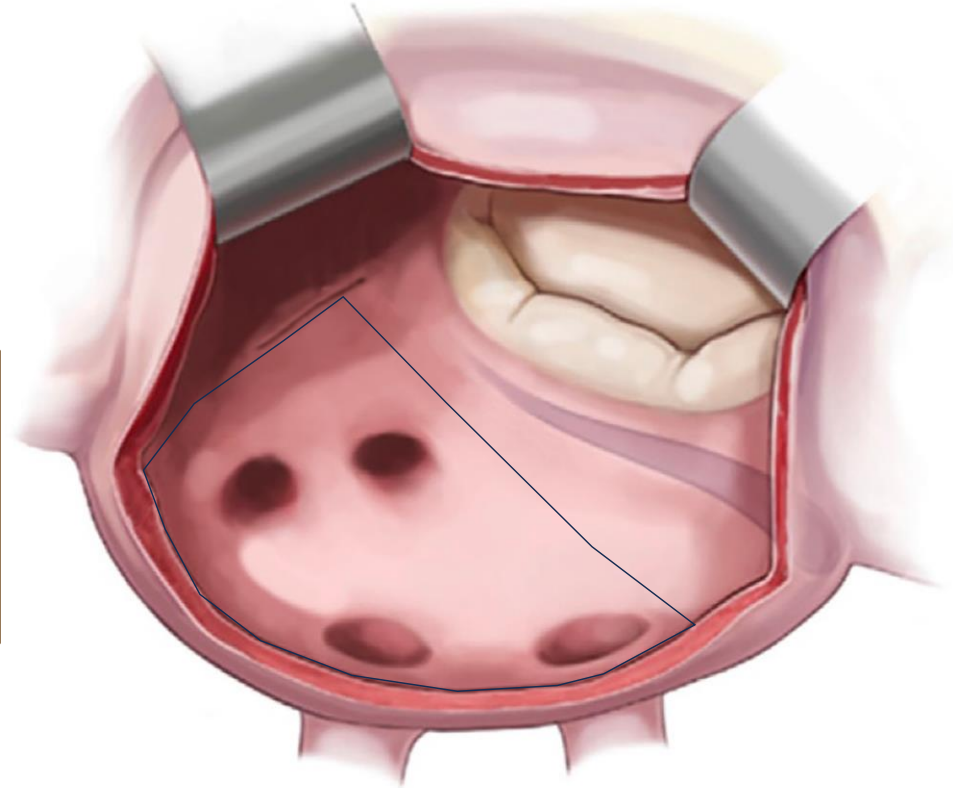
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PWI

## ADVANTAGES

Non-Atriotomy  
No Posterior Dissection  
No Additional XC  
No Change In Cannulation

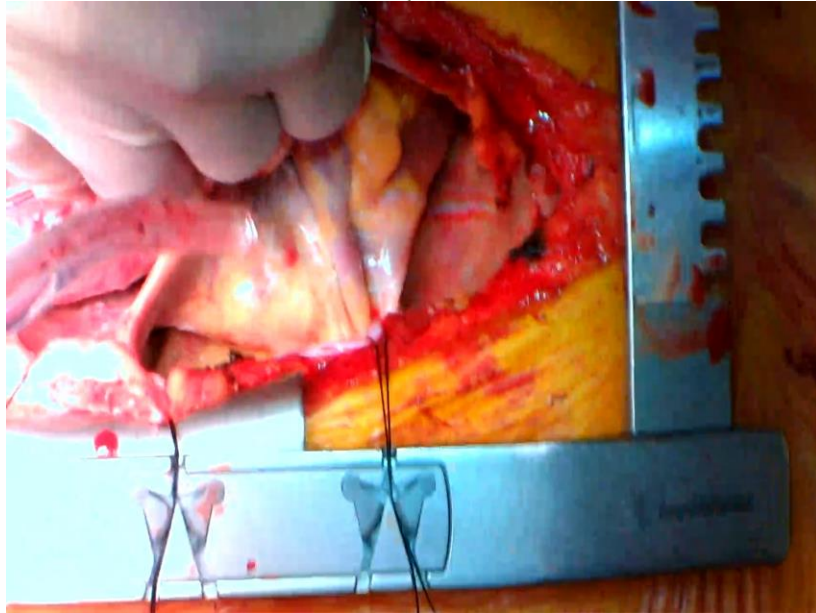




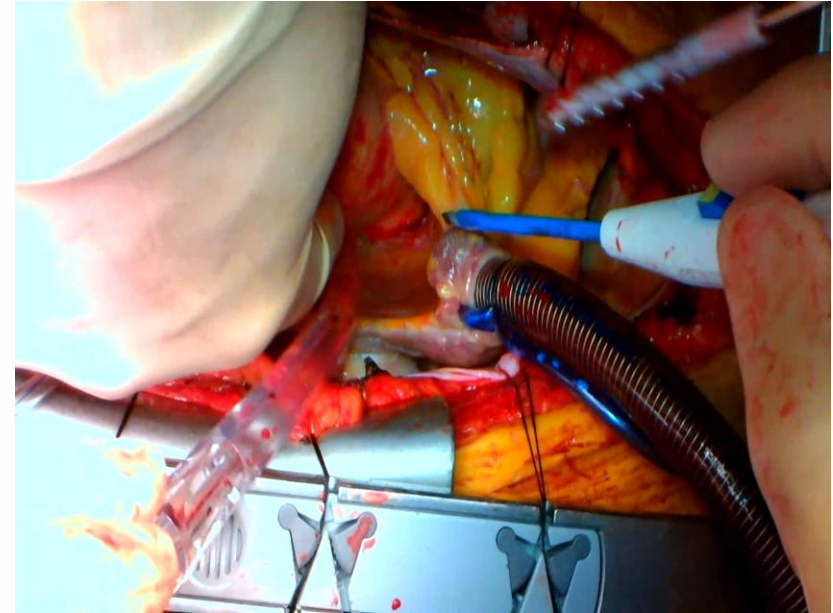
# Fundamentals of Non-Atriotomy Surgical Ablation

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OBLIQUE SINUS



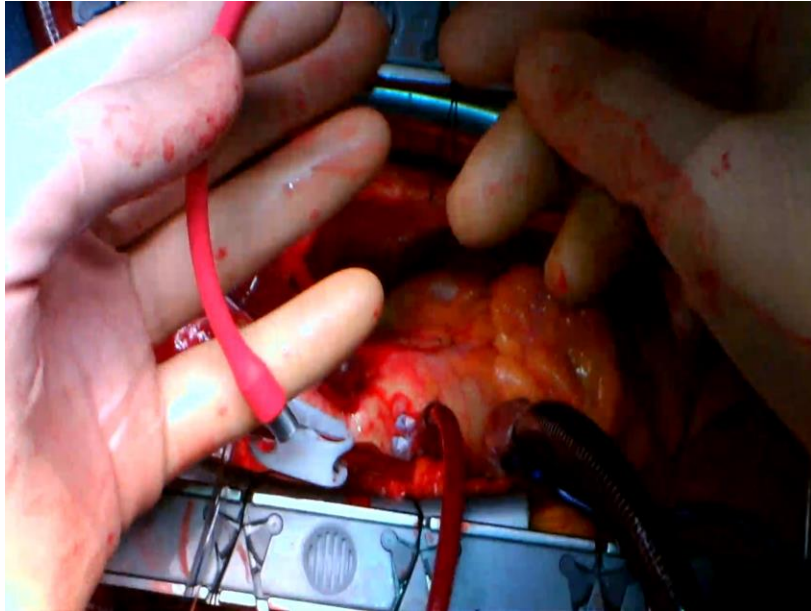
TRANSVERSE SINUS



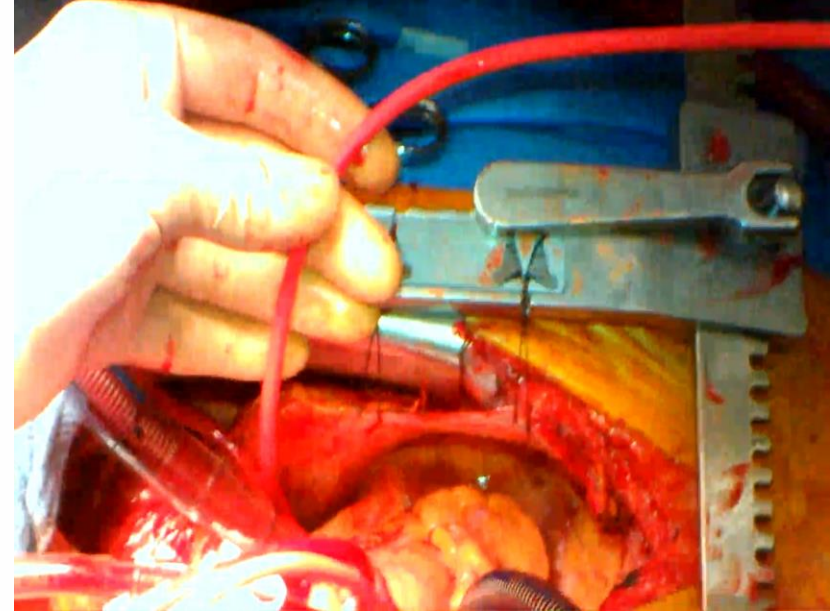
# Fundamentals of Non-Atriotomy Surgical Ablation

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GUIDE PLACEMENT TS

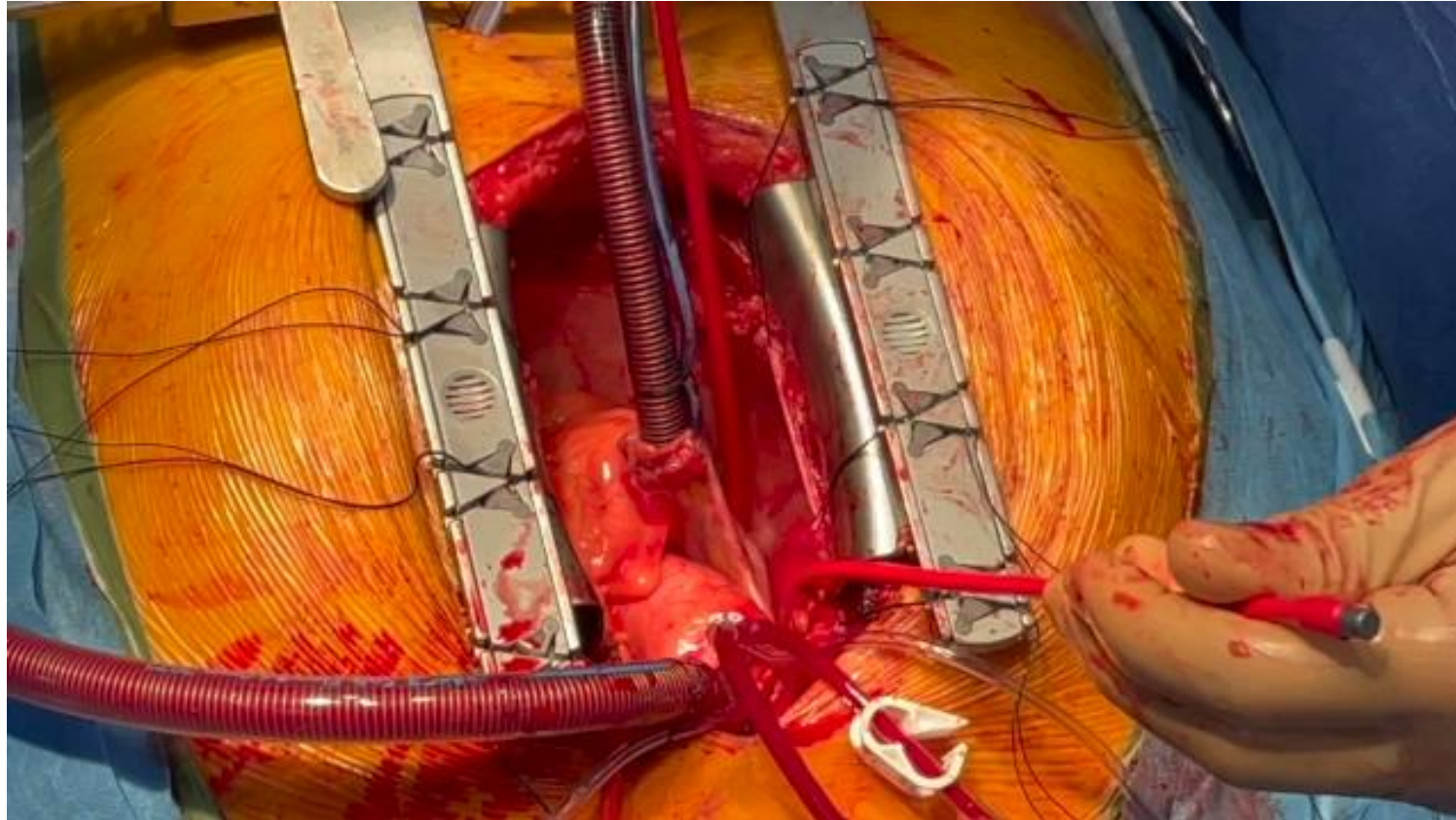


GUIDE PLACEMENT OS



# Fundamentals of Non-Atriotomy Surgical Ablation

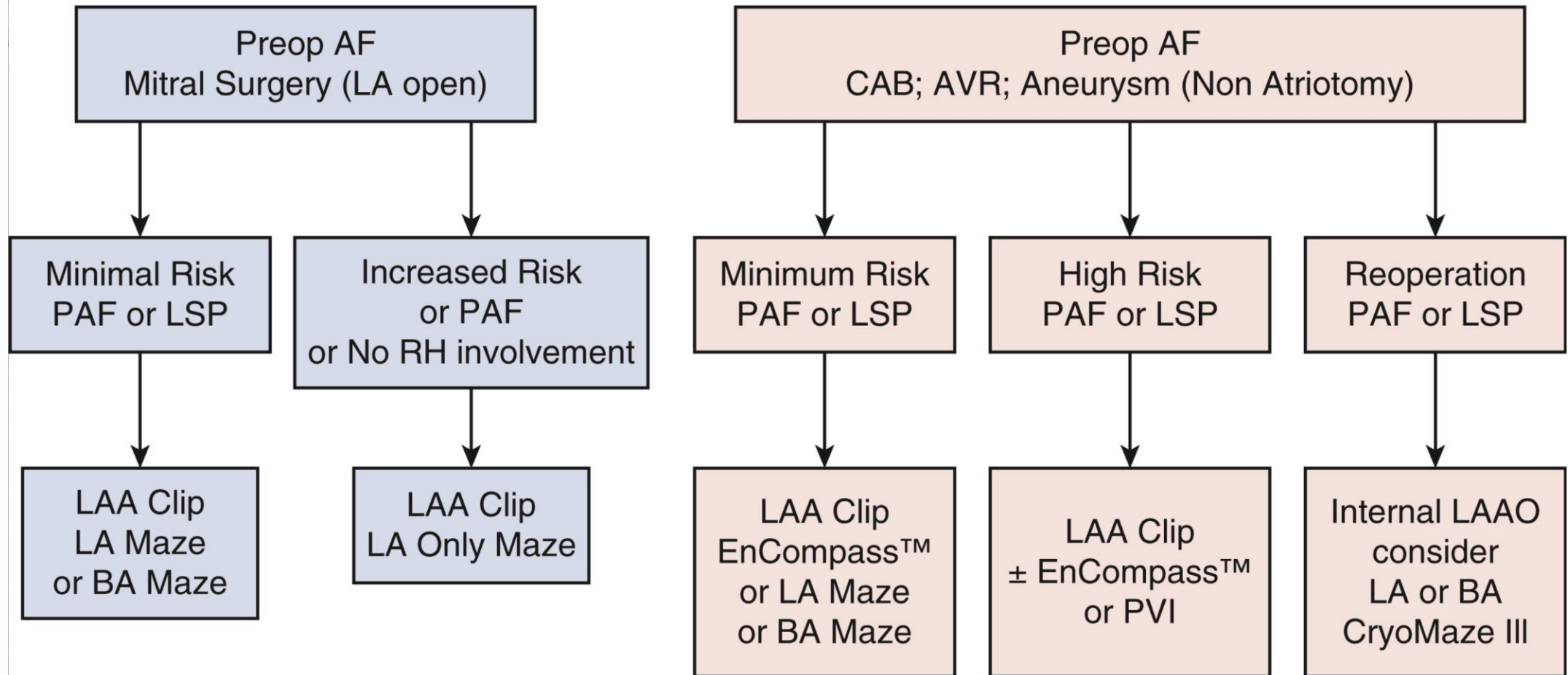
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# Matching Ablation to the Patient

## Concomitant Atrial Fibrillation Treatment Decision Making



# Hybrid Convergent Procedure

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# Hybrid AF Therapy: Staged Approach

## Stage 1: Epicardial Ablation

- Posterior Wall Isolation
- Left Atrial Appendage Exclusion (LAAE)

## Stage 2: Endocardial Ablation

- Completion of PVI and silencing of any residual posterior wall activity

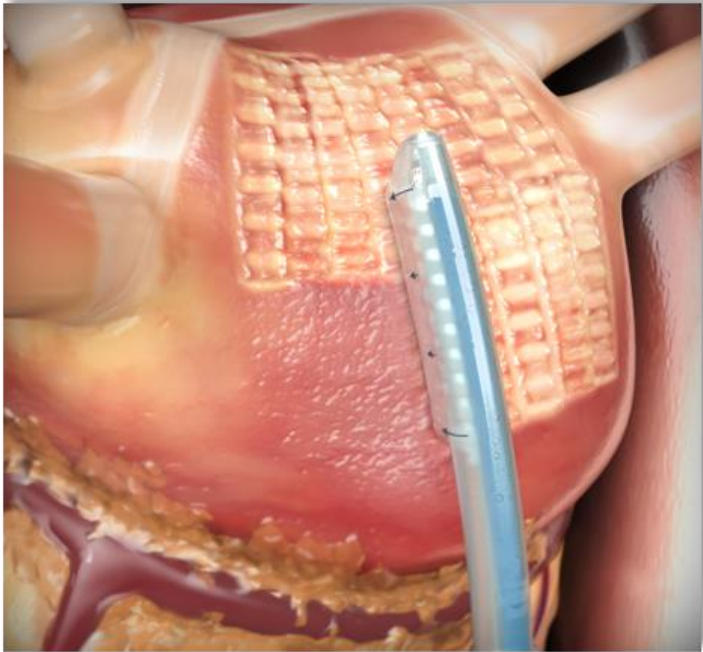
Hybrid Convergent Procedure can be done same day or sequentially

- Epicardial ablation time and hospital length of stay shorter than full hybrid ablation
- Less invasive as well

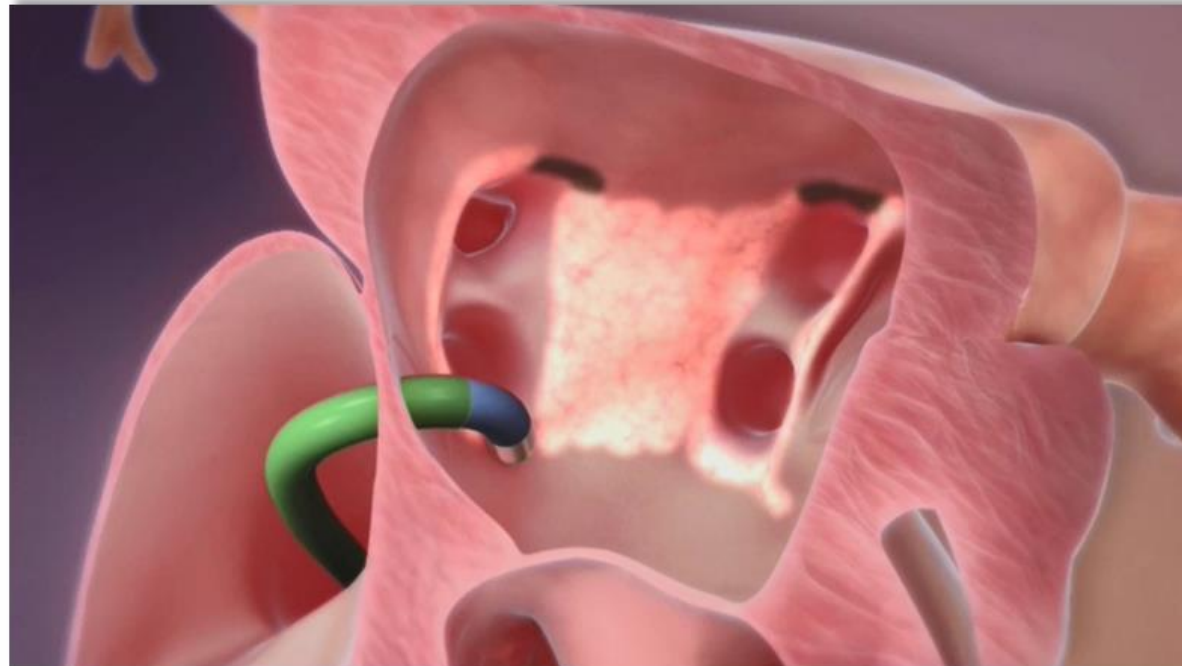
# Hybrid AF Therapy

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The Hybrid AF Convergent Therapy procedure combines endocardial and epicardial ablation to achieve a more comprehensive intervention while minimizing risk of esophageal injury.



The epicardial ablation is conducted by a cardiac surgeon via subxiphoid access to the pericardium.

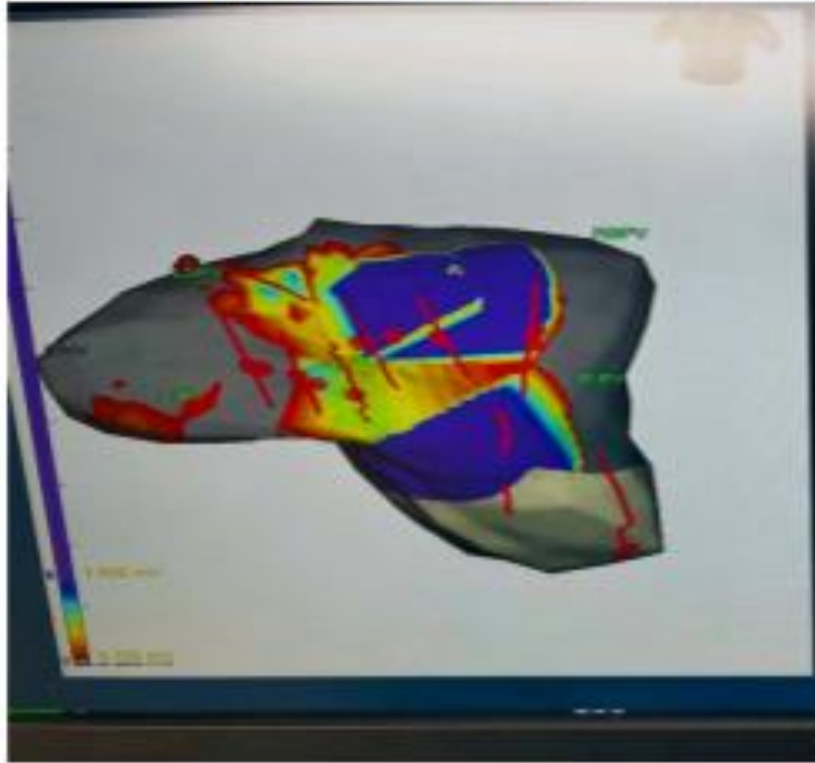


The endocardial procedure is conducted by an electrophysiologist via percutaneous access.

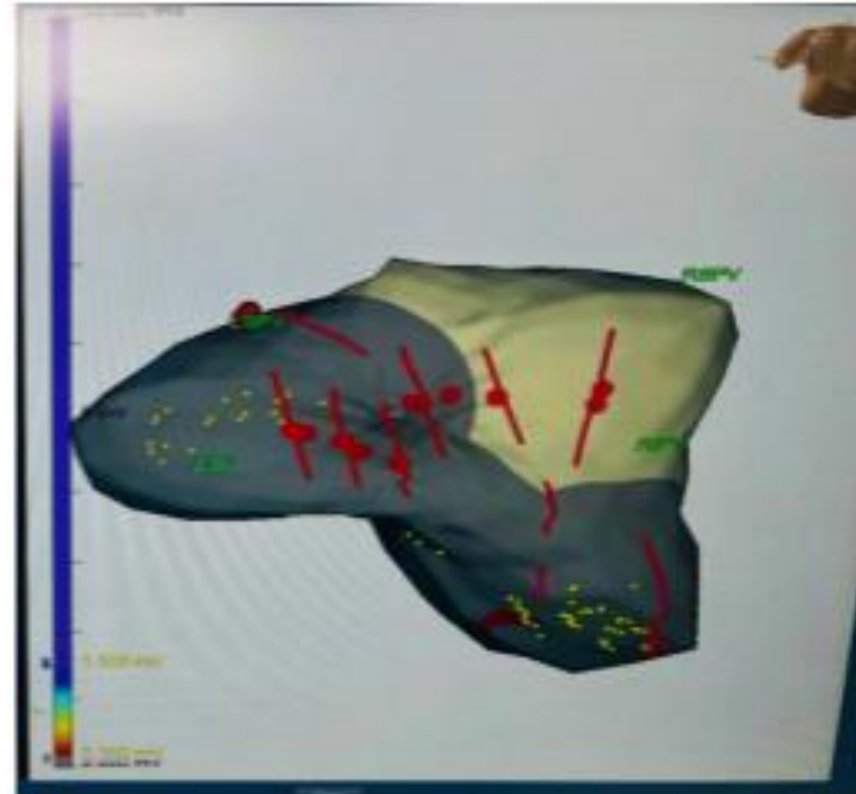
# Electrical Activity Post Hybrid AF Therapy

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Pre-Epicardial Mapping



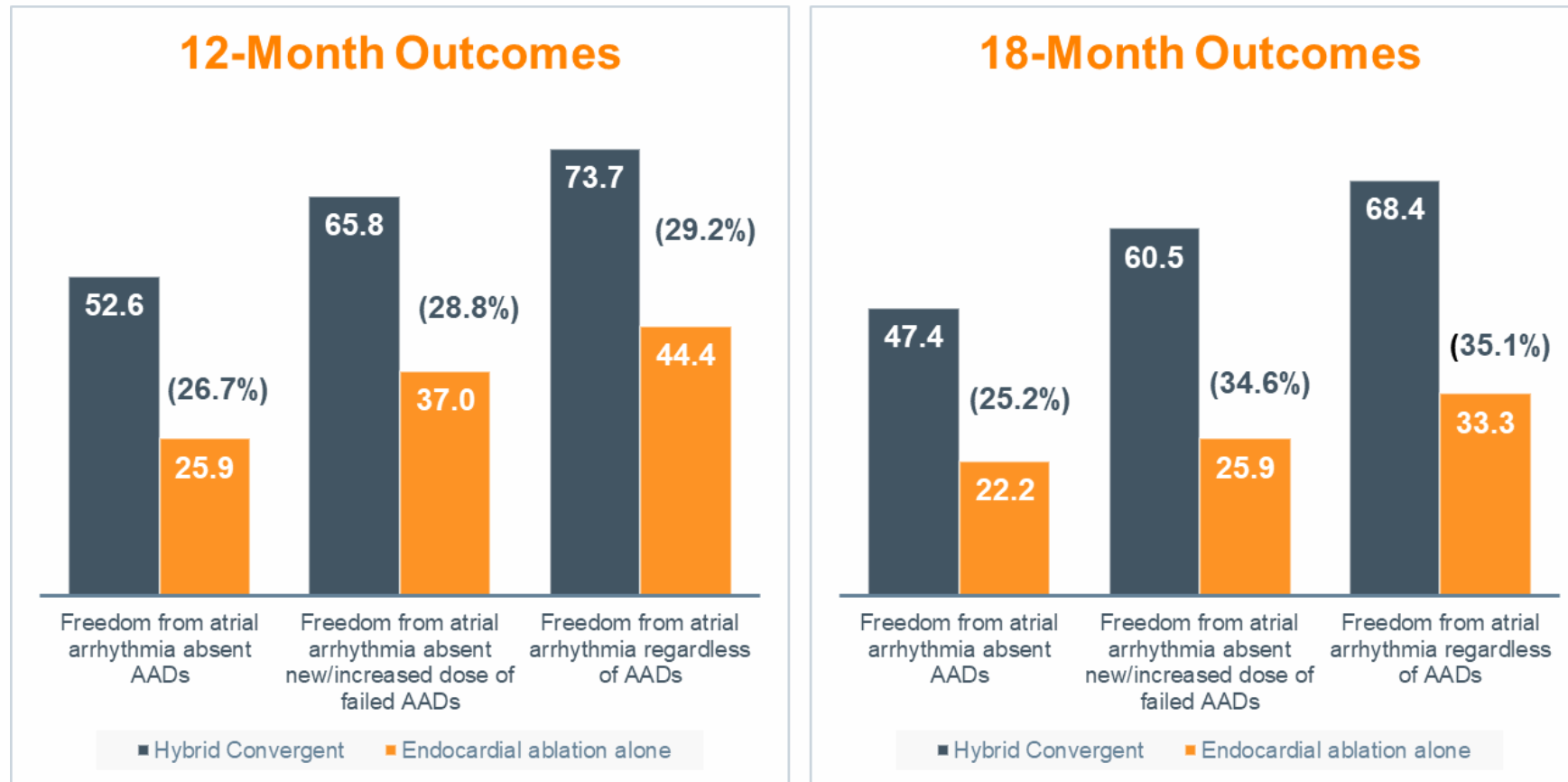
Post-Epicardial Mapping





# Convergent Procedure

# CONVERGE



Freedom from atrial arrhythmia with and/or without AADs was notably higher with Hybrid AF Convergent Vs endocardial ablation alone, and sustained through 18 months (7-day Holter)

Data based on the post-hoc analysis of long-standing persistent AF sub-groups (N=65)

IFU for EPi-Sense® Guided Coagulation System Data: PMA# P200002

# Management of Left Atrial Appendage

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## HOW COULD AFIB AFFECT YOU?

IN THE  
UNITED STATES  
ALONE,



**15-20%**  
OF STROKES ARE  
DUE TO AFIB.

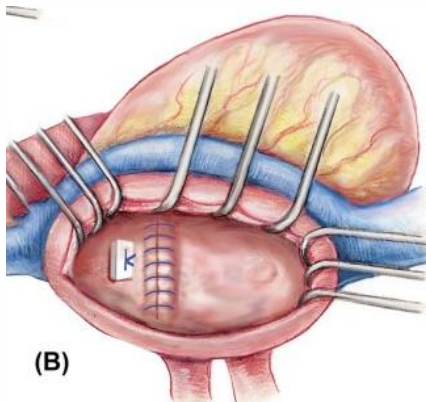
Source: What is Atrial Fibrillation (AFib or AF)? 2016 Jul 23. American Heart Association. Retrieved from <https://www.heart.org/en/health-topics/atrial-fibrillation/what-is-atrial-fibrillation-afib-or-af#.V1sWTsfCTww>.

#AfibAwarenessMonth

# Left Atrial Appendage Management

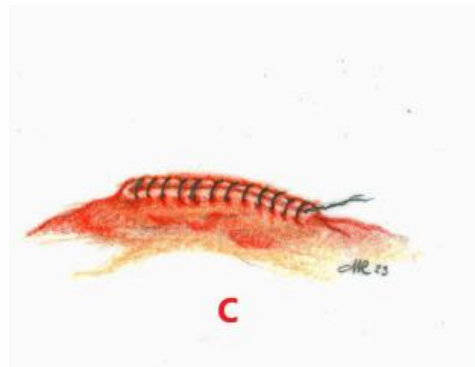
## Endocardial Management

- Occlude interior opening to left atrial appendage



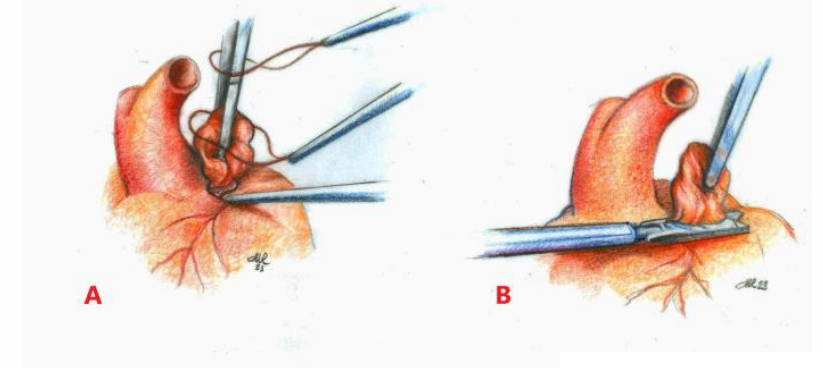
## Surgical Closure

- Cut and Sew over Epicardial/Endocardial LAA
- Cut and Staple over Exterior LAA

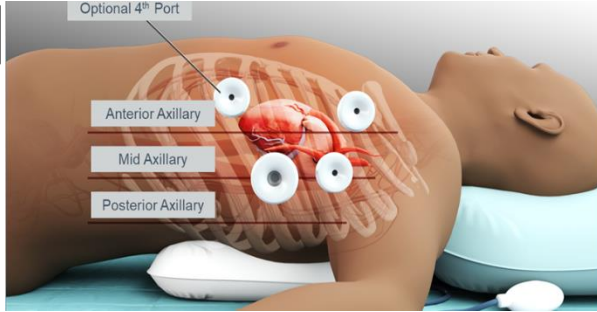


## Epicardial Management

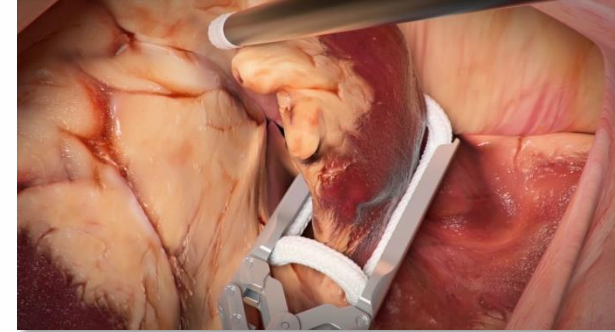
- Device applied to exclude structure epicardially



# Min 1 al App 2 age Exclusion



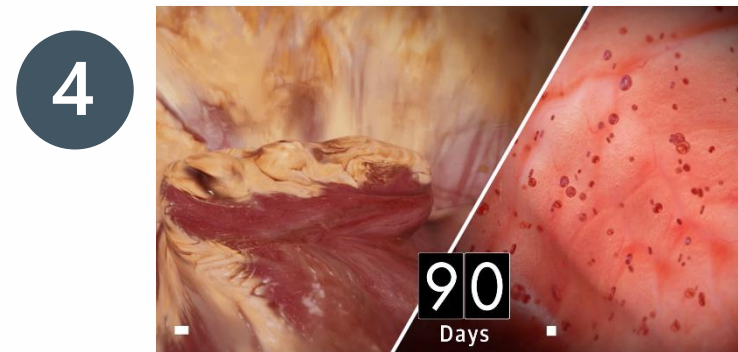
3-4 small ports placed in between left ribs



Pericardial access with clip placement



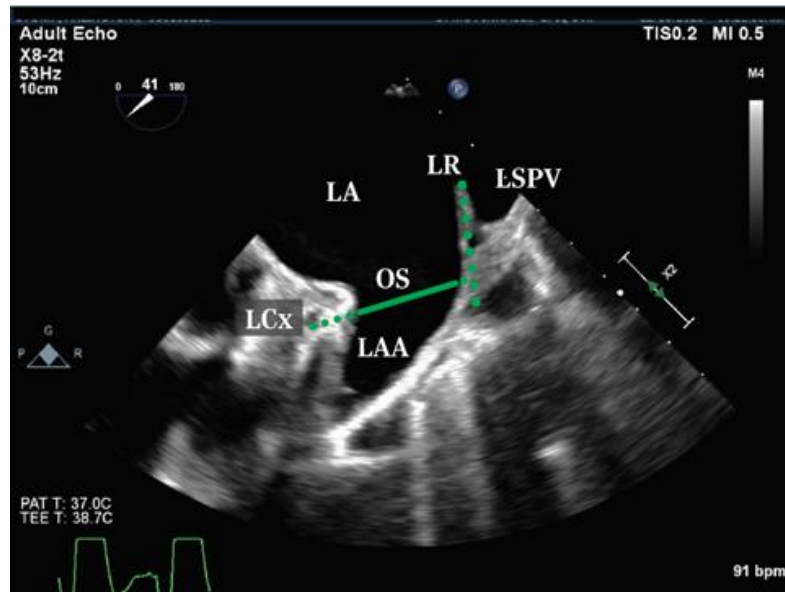
LAA exclusion resulting in electrical isolation



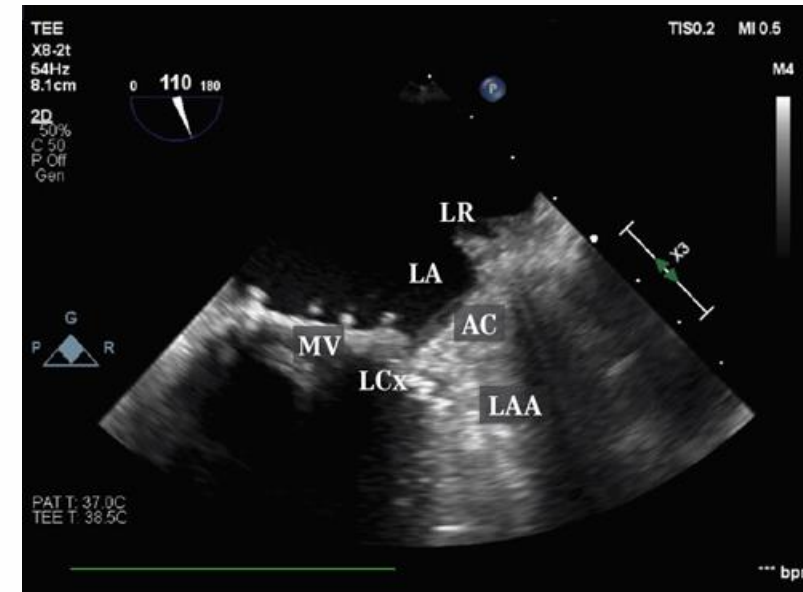
Appendage is reabsorbed into cardiac tissue



# AtriClip Placement & TEE Assessment



**BEFORE**



**AFTER**

## Successful Placement

- No flow exiting LAA
- No or minimized residual cul-de-sac of the main LAA (<1.0cm)
- No adjacent anatomical structures have been affected by the device.

# AtriClip Closure Rates

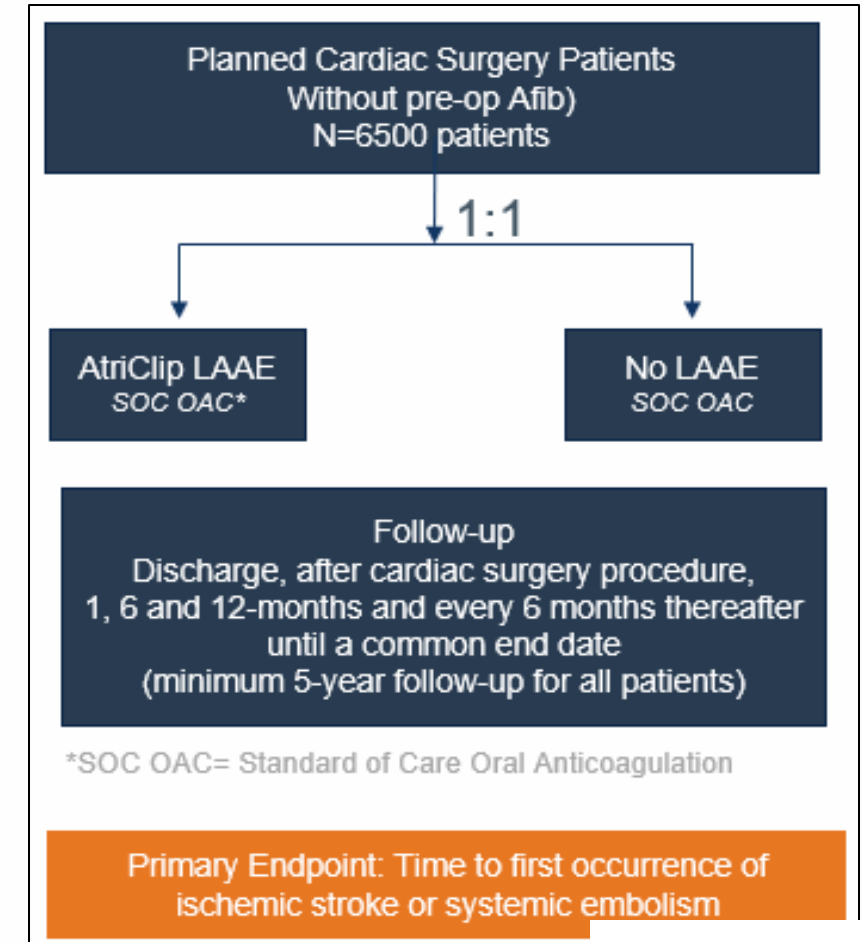
Reference	Results
Ailawadi (2011) <sup>1</sup>	<ul style="list-style-type: none"><li>• 98.4% successful LAA closure</li><li>• 3 month follow-up</li></ul>
Caliskan (2017) <sup>2</sup>	<ul style="list-style-type: none"><li>• 100% successful close rate</li><li>• More than 5 years follow-up</li></ul>
van Laar (2018) <sup>3</sup>	<ul style="list-style-type: none"><li>• 95% successful LAA closure rate</li><li>• 6 month follow-up</li></ul>
Ellis (2017) <sup>4</sup>	<ul style="list-style-type: none"><li>• 93.9% successful LAA closure rate</li><li>• 183 patient years follow-up</li></ul>
Kurfirst (2017) <sup>5</sup>	<ul style="list-style-type: none"><li>• 98% successful LAA closure rate</li><li>• 18 month follow-up</li></ul>
Emmert (2013) <sup>6</sup>	<ul style="list-style-type: none"><li>• 100% successful LAA closer</li><li>• 3.5 year follow-up</li></ul>

Reference	Results
Ad (2015) <sup>7</sup>	<ul style="list-style-type: none"><li>• 100% successful LAA closure</li><li>• 1 year follow-up</li></ul>
Gerdisch (2017) <sup>8</sup>	<ul style="list-style-type: none"><li>• 98.7% successful LAA closure</li><li>• 30 day follow-up</li></ul>
Mokracek (2015) <sup>9</sup>	<ul style="list-style-type: none"><li>• 93% successful LAA closure</li><li>• 11 month follow-up</li></ul>
Page (2017) <sup>10</sup>	<ul style="list-style-type: none"><li>• 100% successful LAA closure</li><li>• More than 1 year follow-up</li></ul>
Beaver (2016) <sup>11</sup>	<ul style="list-style-type: none"><li>• 100% successful closure</li><li>• 1 year follow-up</li></ul>

# LEAAPS Trial

This trial aims to determine the effectiveness of LAAE with AtriClip® at the time of cardiac surgery for the prevention of ischemic stroke or systemic arterial embolism in patients with atrial cardiomyopathy, without a clinical history of Afib, but with risk factors for Afib and ischemic stroke.

<b>Study Design</b>	Prospective, multicenter, international, blinded, event-driven, superiority IDE trial; patients randomized 1:1 to receive LAAE with AtriClip® during planned cardiac surgery or undergo cardiac surgery without LAAE
<b>Primary Effectiveness Endpoint</b>	Time to the first occurrence of ischemic stroke or systemic arterial embolism as adjudicated by a CEC, or any procedure wherein the LAA was excluded, occluded, or amputated following the index procedure.
<b>Primary Safety Endpoint</b>	Occurrence of at least one of the following events assessed through 30 days post-index procedure: <ul style="list-style-type: none"><li>• Pericardial effusion requiring percutaneous or surgical treatment</li><li>• Major bleeding attributable to index surgical procedure</li><li>• Deep sternal wound infection</li><li>• Myocardial infarction</li></ul>
<b>Sample Size and Sites</b>	Up to 6500 patients at up to 250 US and OUS sites



US FDA IDE#: G220093

Clinicaltrials.gov identifier: NCT05478304

Thank you

