Surgical Options for AF Management in Contemporary Practice

Virginia Mason Franciscan Health™
Center for Cardiovascular Health

Surgical Options for AF Management in Contemporary Practice

R. Christopher King, MD
Center for Cardiovascular Health
St Michael Medical Center, Silverdale, WA

Virginia Mason Franciscan Health Atrial Fibrillation (AF) Program

- Improve the quality of life and longevity of our AF patient population by creating access to best practice personalized care.
- Deliver multidisciplinary treatment pathways while embracing new technologies.
- Decrease the significant financial impact of costly admissions by implementing effective AF referral pathways.

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PM-US-1528B-0923-G

Atrial Fibrillation

Self-perpetuating, progressive, systemic, multifactorial, dangerous disease leading to:

- Diminished quality of life[4-8]
- Shorter lifespan

5x
Greater Risk of Stroke[9]

5x
Greater Risk of CHF[10]

46%
Greater Risk of Death[10]

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AF: Economic Burden in the United States

By 2030, there will be an estimated **12 million** people in the U.S. with Afib[2]

564,000 ED visits per year[12]

450,000+ hospitalizations per year where the primary diagnosis is Afib[9]

470,000, or **~65%** of Afib patients presenting to the ED are admitted each year[13]

Afib patients cost **$8,700** more per year to treat[11]

Afib costs the U.S. health system **$26 billion** per year[11]

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Progression of AF

Paroxysmal (30%)[1]
2.4 M Patients
Occurs occasionally and can last up to 7 days

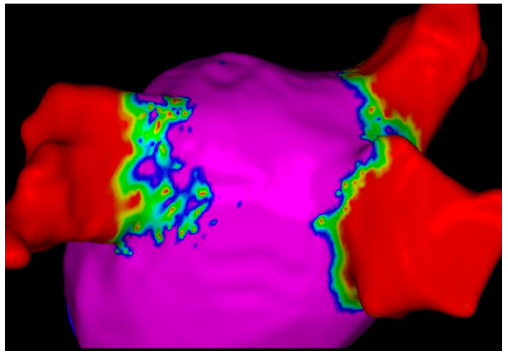
Persistent (25%)[1]
2.0 M Patients
Lasts beyond 7 days and as long as 1 year

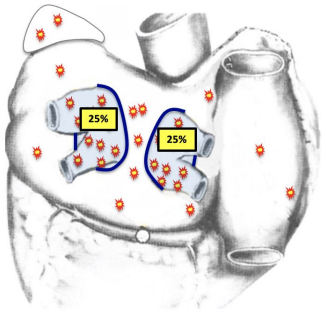
Long-Standing Persistent (45%)[1]
3.6 M Patients
Lasts longer than 1 year without stopping

PV Triggers

Non-PV Triggers
Substrate Remodeling
Sustained by Drivers

PVI





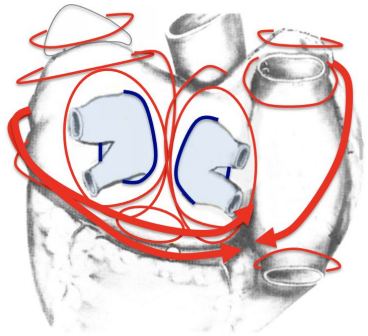
Pulmonary vein triggers

Haissaguerre, NEJM 1998

Non-PVI

PVI
Isolates
< 50% of Triggers

PVI
Interrupts
0% of Drivers



CLASS (STRENGTH) OF RECOMMENDATION

CLASS I (STRONG) — **Benefit >>> Risk**

Suggested phrases for writing recommendations:
- Is recommended
- Is indicated/useful/effective/beneficial
- Should be performed/administered/other
- Comparative-Effectiveness Phrases†:
  - Treatment/strategy A is recommended/indicated in preference to treatment B
  - Treatment A should be chosen over treatment B

CLASS IIa (MODERATE) — **Benefit >> Risk**

Suggested phrases for writing recommendations:
- Is reasonable
- Can be useful/effective/beneficial
- Comparative-Effectiveness Phrases†:
  - Treatment/strategy A is probably recommended/indicated in preference to treatment B
  - It is reasonable to choose treatment A over treatment B

CLASS IIb (WEAK) — **Benefit ≥ Risk**

Suggested phrases for writing recommendations:
- May/might be reasonable
- May/might be considered
- Usefulness/effectiveness is unknown/unclear/uncertain or not well established

CLASS III: No Benefit (MODERATE) — **Benefit = Risk**
(Generally, LOE A or B use only)

Suggested phrases for writing recommendations:
- Is not recommended
- Is not indicated/useful/effective/beneficial
- Should not be performed/administered/other

CLASS III: Harm (STRONG) — **Risk > Benefit**

Suggested phrases for writing recommendations:
- Potentially harmful
- Causes harm
- Associated with excess morbidity/mortality
- Should not be performed/administered/other

LEVEL (QUALITY) OF EVIDENCE‡

LEVEL A
- High-quality evidence‡ from more than 1 RCT
- Meta-analyses of high-quality RCTs
- One or more RCTs corroborated by high-quality registry studies

LEVEL B-R (Randomized)
- Moderate-quality evidence‡ from 1 or more RCTs
- Meta-analyses of moderate-quality RCTs

LEVEL B-NR (Nonrandomized)
- Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analyses of such studies

LEVEL C-LD (Limited Data)
- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analyses of such studies
- Physiological or mechanistic studies in human subjects

LEVEL C-EO (Expert Opinion)

Consensus of expert opinion based on clinical experience

COR and LOE are determined independently (any COR may be paired with any LOE).

A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

* The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).

† For comparative-effectiveness recommendations (COR I and IIa; LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

‡ The method of assessing quality is evolving, including the application of standardized, widely used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

COR indicates Class of Recommendation; EO, expert opinion; LD, limited data; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.

What are the Current Society of Thoracic Surgeons Recommendations for the Surgical Ablation of Atrial Fibrillation

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SPECIAL REPORT

The Society of Thoracic Surgeons 2017 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation

Vinay Badhwar, MD, J. Scott Rankin, MD, Ralph J. Damiano, Jr, MD, A. Marc Gillinov, MD, Faisal G. Bakaeen, MD, James R. Edgerton, MD, Jonathan M. Philpott, MD, Patrick M. McCarthy, MD, Steven F. Bolling, MD, Harold G. Roberts, MD, Vinod H. Thourani, MD, Rakesh M. Suri, MD, DPhil, Richard J. Shemin, MD, Scott Firestone, MS, Niv Ad, MD

Division of Cardiothoracic Surgery, West Virginia University, Morgantown, West Virginia (VB, JSR, NA); Division of Cardiothoracic Surgery, Washington University, St. Louis, Missouri (RJD); Division of Thoracic and Cardiovascular Surgery, Cleveland Clinic, Cleveland, Ohio (AMG, FGB, RMS); Department of Cardiothoracic Surgery, Baylor Plano Heart Hospital, Plano, Texas (JRE); Department of Cardiothoracic Surgery, Sentara Heart Hospital, Norfolk, Virginia (JMP); Division of Cardiac Surgery, Northwestern University Feinberg School of Medicine, Chicago, Illinois (PMM); Department of Cardiac Surgery, University of Michigan, Ann Arbor, Michigan (SFB); Department of Cardiovascular Services, Florida Heart and Vascular Care at Aventura, Aventura, Florida (HGR); Division of Cardiothoracic Surgery, Emory University, Atlanta, Georgia (VHT); Division of Cardiothoracic Surgery, University of California Los Angeles David Geffen School of Medicine, Los Angeles, California (RJS); and The Society of Thoracic Surgeons, Chicago, Illinois (SF)

Executive Summary

Surgical ablation for atrial fibrillation (AF) can be per-
hout additional risk of operative mortality or
idity, and is recommended at the time of
mitral operations to restore sinus rhythm.

using the Cox-Maze III/IV lesion set compared with pulmonary vein isolation alone. (Class IIA, Level B nonrandomized)

Surgical ablation for symptomatic AF in the setting of left atrial enlargement (≥4.5 cm) or more than moderate mitral regurgitation by pulmonary vein isolation alone is

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CLINICAL PRACTICE GUIDELINE

The Society of Thoracic Surgeons 2023 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation

Moritz C. Wyler von Ballmoos, MD, PhD,[1] Dawn S. Hui, MD,[2] J. Hunter Mehaffey, MD, MSc,[3] S. Chris Malaisrie, MD,[4] Panos N. Vardas, MD,[5] A. Marc Gillinov, MD,[6] Thoralf M. Sundt, MD,[7] and Vinay Badhwar, MD[3]

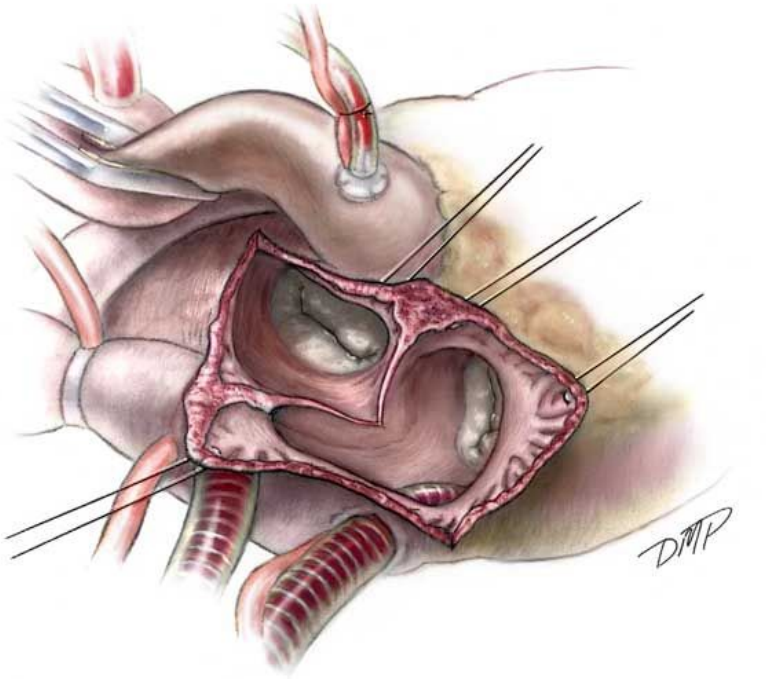
The Society of Thoracic Surgeons 2023 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation incorporate the most recent evidence for surgical ablation and left atrial appendage occlusion in different clinical scenarios. Substantial new evidence regarding the risks and benefits of surgical left atrial appendage occlusion and the long-term benefits of surgical ablation has been produced in the last 5 years. Compared with the 2017 clinical practice guideline, the current update has an emphasis on surgical ablation in first-time, nonemergent cardiac surgery and its long-term benefits, an extension of the recommendation to perform surgical ablation in all patients with atrial fibrillation undergoing first-time, nonemergent cardiac surgery, and a new class I recommendation for left atrial appendage occlusion in all patients with atrial fibrillation undergoing first-time, nonemergent cardiac surgery. Further guidance is provided for patients with structural heart disease and atrial fibrillation being considered for transcatheter valve repair or replacement, as well as patients in need of isolated left atrial appendage management who are not candidates for surgical ablation. The importance of a multidisciplinary team assessment, treatment planning, and long-term follow-up are reiterated in this clinical practice guideline with a class I recommendation, along with the other recommendations from the 2017 guidelines that remained unchanged in their class of recommendation and level of evidence.

(Ann Thorac Surg 2024;118:291-311)

EXECUTIVE SUMMARY

In 2017, The Society of Thoracic Surgeons (STS) published the Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation.[1] This

databases have studied the association of surgical ablation and longer-term outcomes in patients with atrial fibrillation undergoing concomitant cardiac surgery procedures.



2023 Surgical AF Guidlines

Recommendations for mitral valve operations:

1. **Surgical ablation for atrial fibrillation is recommended for first-time nonemergent concomitant *mitral operations* to restore sinus rhythm and improve long-term outcomes.**
   - **Class of recommendation: I**
   - **Level of evidence: A**

- Decrease Early AF by more than 50%
- 60-80% freedom from AF at 12 months
- Substantial Improvement in long-term QOL
- Survival Benefit
- Better recovery of LV function and LA size regression

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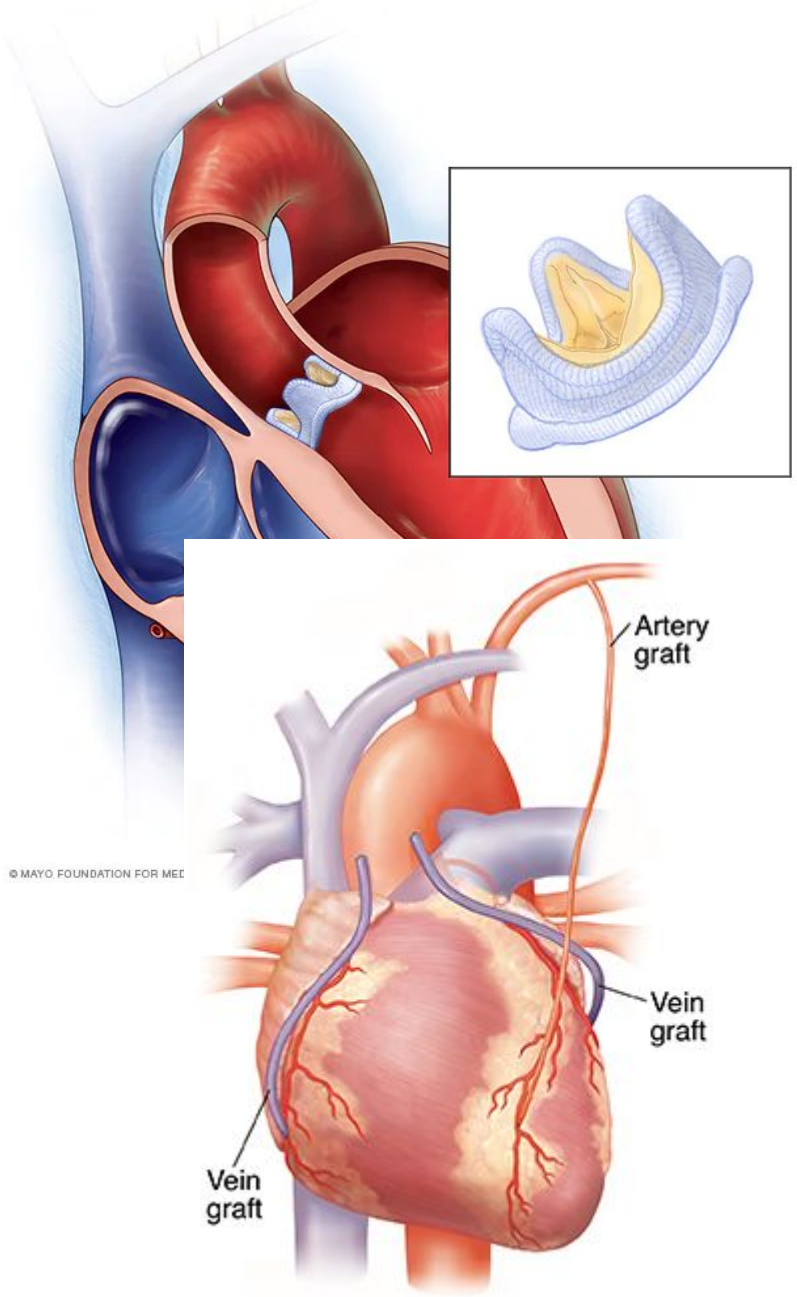


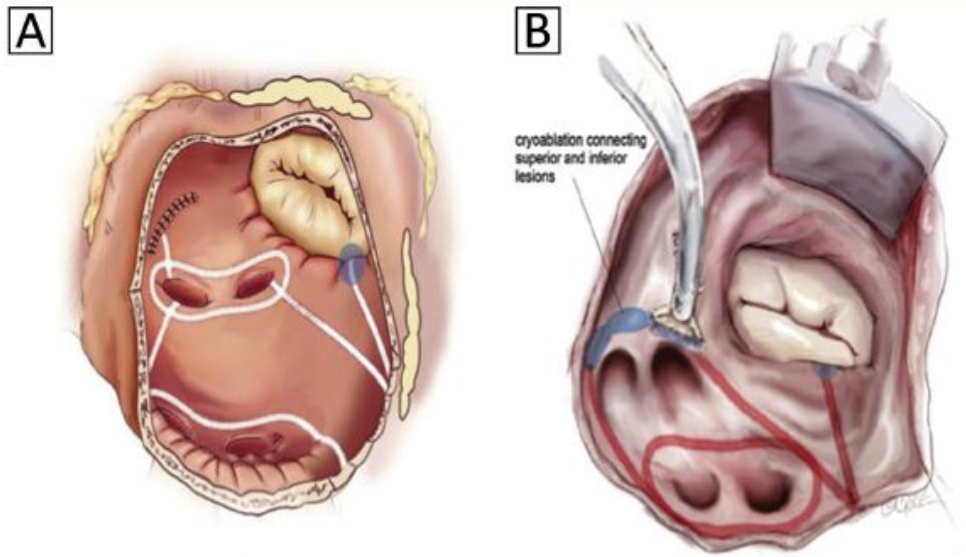
2023 Surgical AF Guidlines

Recommendations for operations other than mitral valve surgery

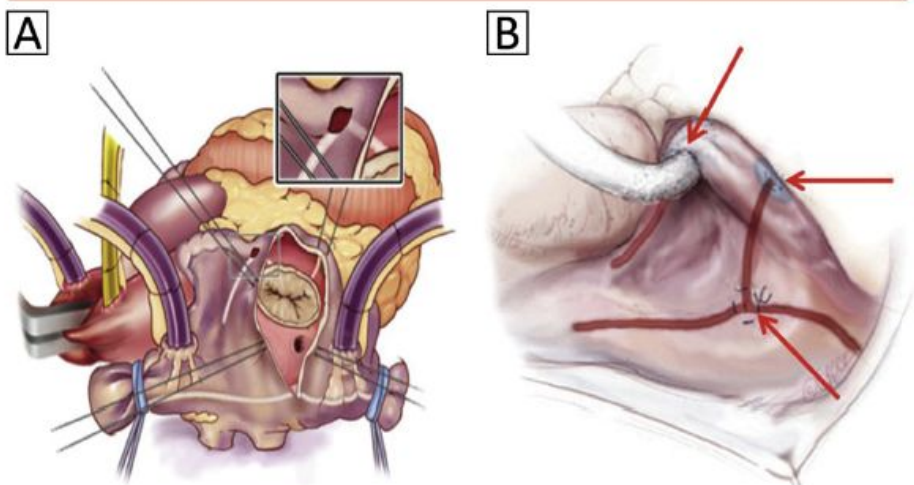
1. **Surgical ablation for atrial fibrillation is recommended for any first-time nonemergent concomitant *nonmitral operation* to restore sinus rhythm and improve long-term outcomes.**
   - **Class of recommendation: I**
   - **Level of evidence: B-NR**

- Decreased all cause mortality at 2 years
- Decreased stroke and thromboembolism
- Established SR in 60-90% of patients technique dependent

Left Atrial Lesion Set



Right Atrial Lesion Set



Sternotomy

Right Mini-thoracotomy

Recommendations regarding stand-alone surgical ablation

1. **Surgical ablation for symptomatic atrial fibrillation in the absence of structural heart disease refractory to class I/III antiarrhythmic drugs, catheter-based therapy, or both, is reasonable as a primary stand-alone procedure to restore sinus rhythm.**
   - **Class of recommendation: IIa**
   - **Level of evidence: B-NR**
2. **Surgical ablation for symptomatic persistent or longstanding persistent atrial fibrillation in the absence of structural heart disease is reasonable as a stand-alone procedure using the Cox maze III/IV lesion set as the preferred procedure.**
   - **Class of recommendation: IIa**
   - **Level of evidence: B-NR**
3. **Surgical ablation for symptomatic atrial fibrillation in the setting of left atrial enlargement (≥4.5 cm) or more than moderate mitral regurgitation by pulmonary vein isolation alone is not recommended.**
   - **Class of recommendation: III**
   - **Level of evidence: C**

2023 Surgical AF Guidlines

Stand Alone Surgical Ablation Results

- Cox Maze IV
  - >90% freedom from AF at 1 year
  - >80% freedom from AF at 5 years
- PVI Only
  - 60% freedom from AF at 1 year
- Hybrid Approach
  - 65-89% freedom from AF at 1 year

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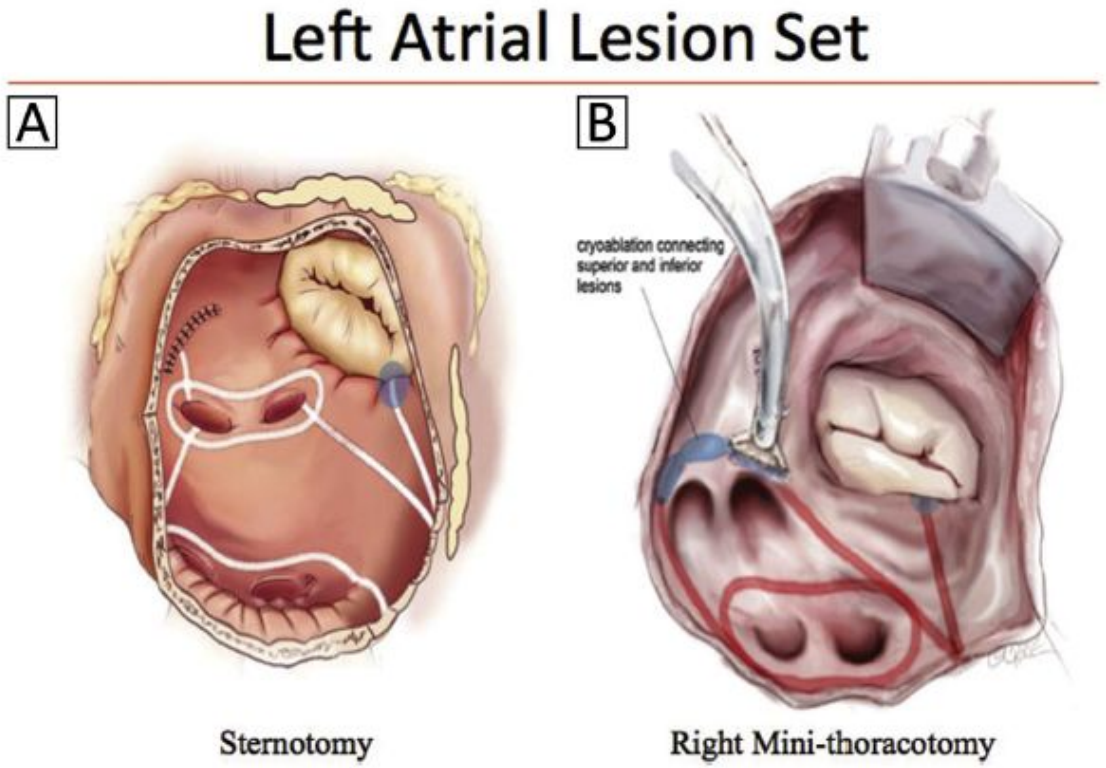
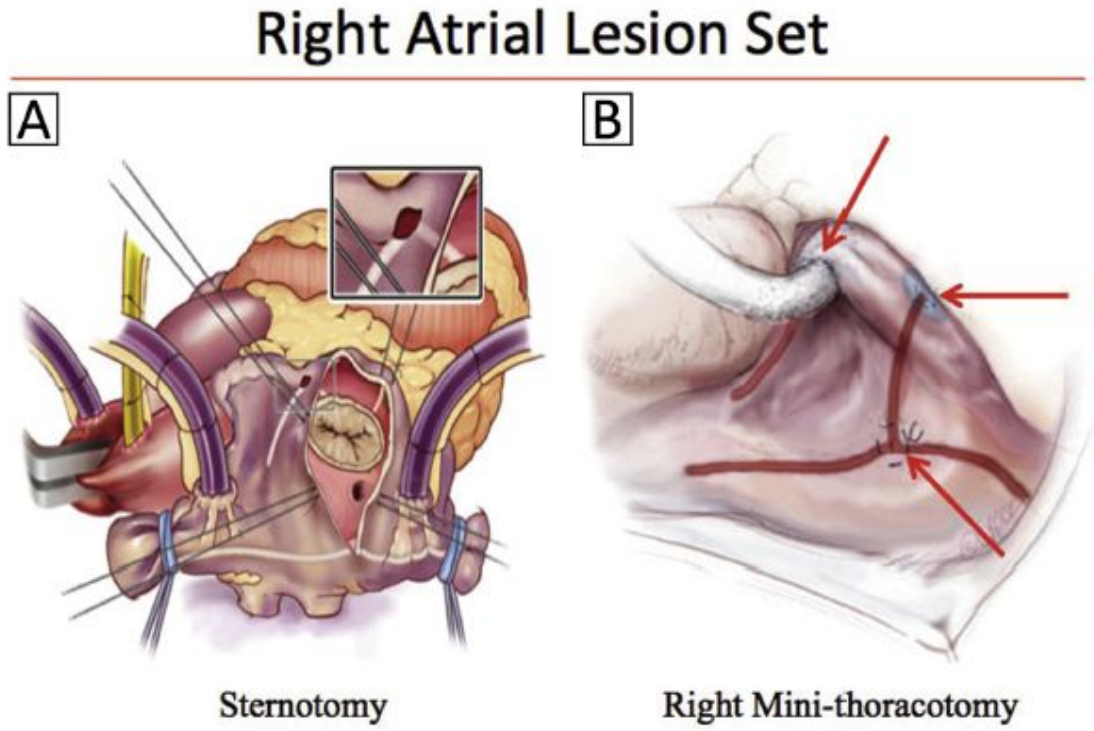
Cox Maze IV Lesion Set





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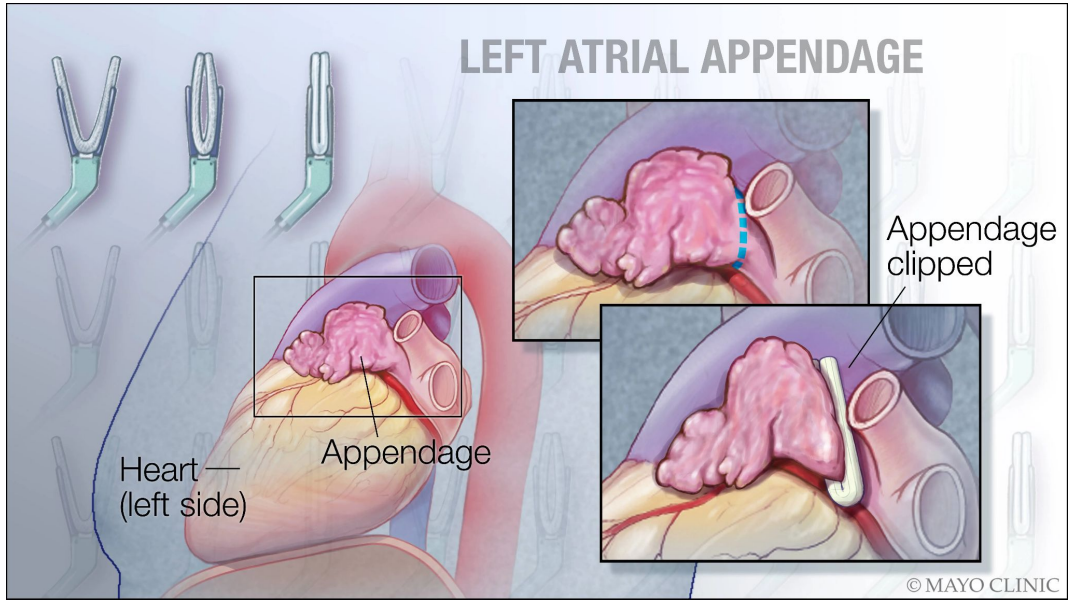
2023 Surgical AF Guidlines



Recommendations for concomitant left atrial appendage management:

1. **Left atrial appendage obliteration for atrial fibrillation is recommended for all first-time non-emergent cardiac surgery procedures, with or without concomitant surgical ablation, to reduce morbidity from thromboembolic complications.**
   - **Class of recommendation: I**
   - **Level of evidence: A**

- Lower all cause mortality
- Lower thromboembolic complications
- Reduced Stroke Rate

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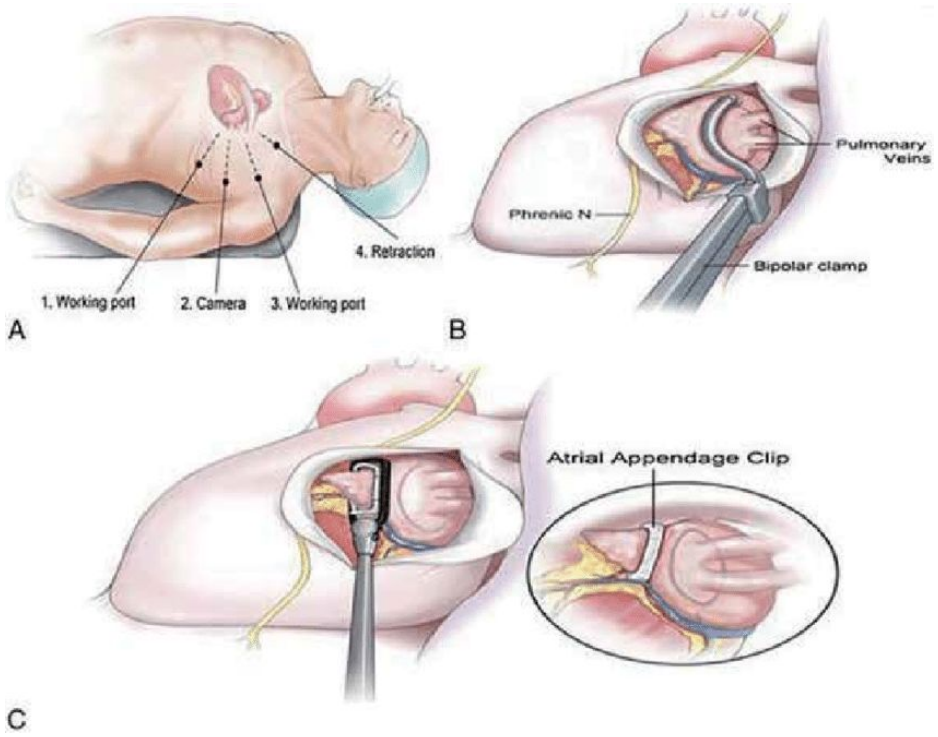
2023 Surgical AF Guidlines



Recommendations regarding stand-alone left atrial appendage management:

1. **Isolated surgical left atrial appendage obliteration may be considered in patients with longstanding persistent atrial fibrillation, a high stroke risk, and contraindications for or failure of long-term oral anticoagulation.**
   - **Class of recommendation: IIb**
   - **Level of evidence: B-NR**

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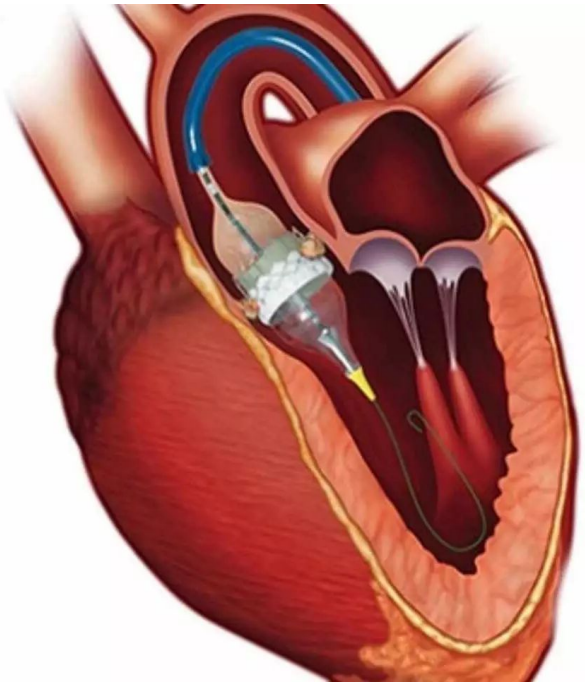
2023 Surgical AF Guidlines



Recommendations for patients being considered for transcatheter valve therapies:

1. **For patients with symptomatic valve disease and atrial fibrillation, who are deemed of low to intermediate surgical risk, surgical valve repair or replacement with concomitant surgical ablation and left atrial appendage occlusion is reasonable over isolated transcatheter valve repair or replacement alone to restore sinus rhythm and improve long-term outcomes.**
   - **Class of recommendation: IIa**
   - **Level of evidence: B-NR**

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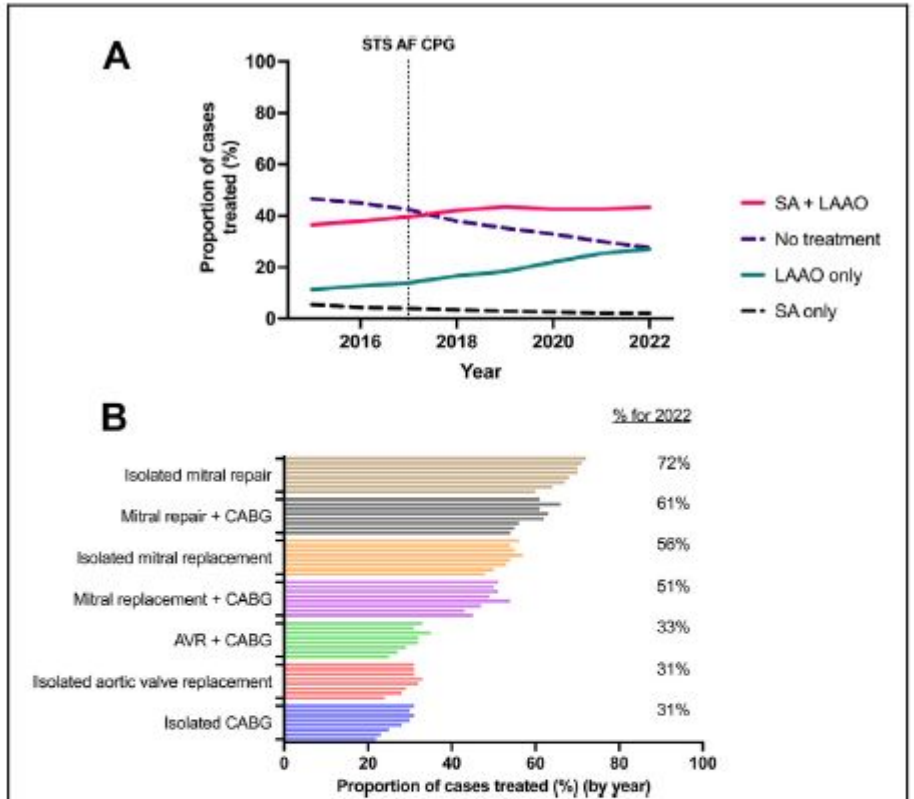

FIGURE 1 Adoption of surgical ablation and left atrial appendage occlusion at first-time, nonemergent heart surgery. (A) Shows the percentage of patients with documented atrial fibrillation undergoing first-time, nonemergent cardiac surgery being treated with surgical ablation (SA), SA + left atrial appendage occlusion (LAAO), LAAO alone, or no treatment. (B) Shows the adoption of complete treatment (SA + LAAO of atrial fibrillation in the same cohort) and by procedure type for each year between 2015 and 2022 (each year represented by one bar). The 2022 percentage of treatment is also listed numerically on the right-hand side of the figure. (AVR, aortic valve replacement; CABG, coronary artery bypass grafting; STS AF CPG, The Society of Thoracic Surgeons 2017 Clinical Practice Guidelines on the Surgical Treatment of Atrial Fibrillation.)

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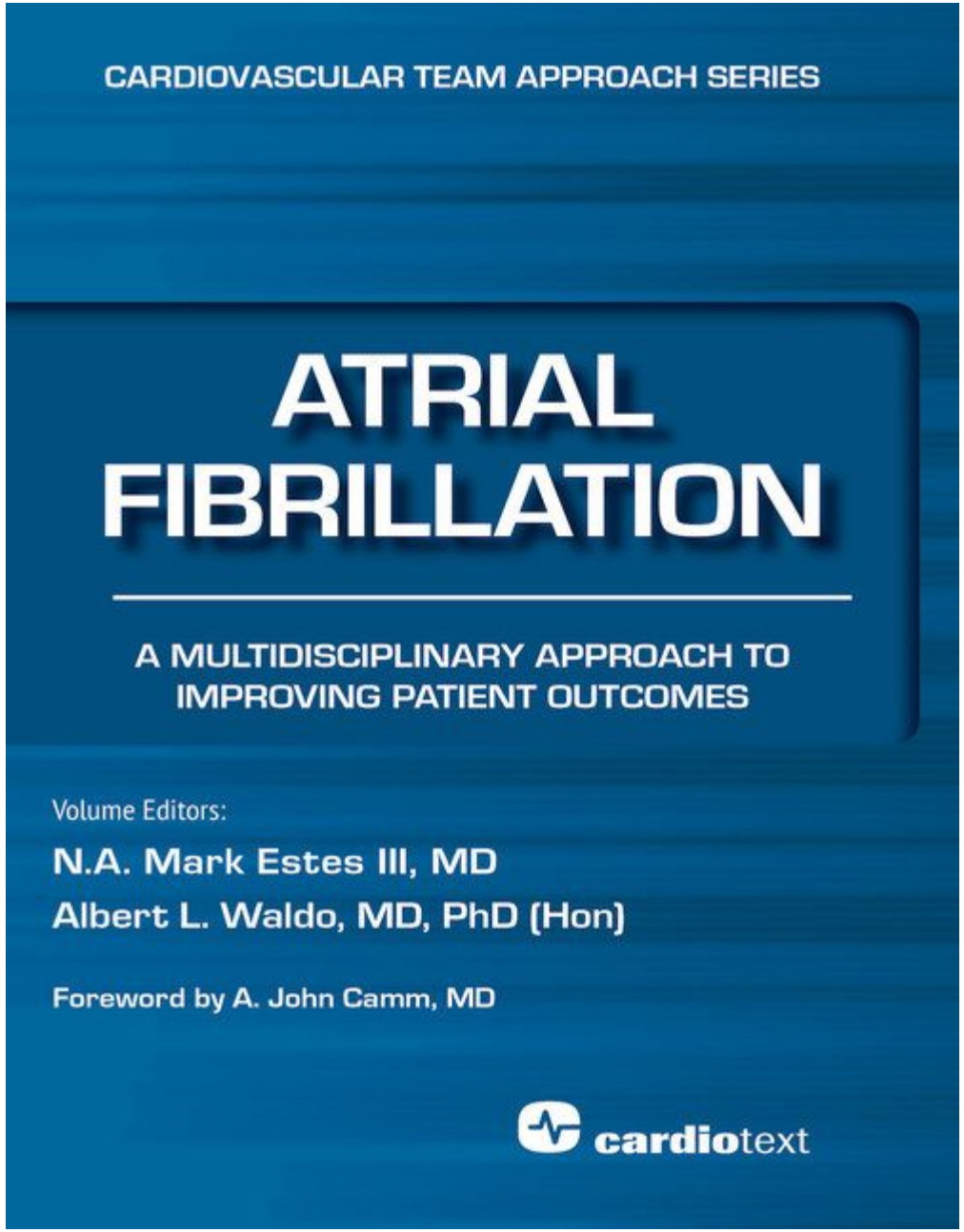

2023 Surgical AF Guidlines

Recommendations for all patients with atrial fibrillation:

1. **Multidisciplinary heart team assessment and treatment planning as well as long-term follow-up using periodic continuous electrocardiographic monitoring for rhythm assessment are recommended to optimize patient outcomes.**
   - **Class of recommendation: I**
   - **Level of evidence: C**

TABLE 2 Updated and New Recommendations in The Society of Thoracic Surgeons 2023 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation

STS 2017 Clinical Practice Guidelines	COR	LOE	STS 2023 Clinical Practice Guidelines	COR	LOE
Recommendations for mitral valve operations:					
Surgical ablation for atrial fibrillation can be performed without additional risk of operative mortality or major morbidity and is recommended at the time of concomitant mitral operations to restore sinus rhythm.	I	A	Surgical ablation for atrial fibrillation is recommended for first-time nonemergent concomitant *mitral operations* to restore sinus rhythm and improve long-term outcomes.	I	A
Recommendations for operations other than mitral valve surgery:					
Surgical ablation for atrial fibrillation can be performed without additional operative risk of mortality or major morbidity and is recommended at the time of concomitant isolated aortic valve replacement, isolated coronary artery bypass graft surgery, and aortic valve replacement plus coronary artery bypass graft operations to restore sinus rhythm.	I	B-NR	Surgical ablation for atrial fibrillation is recommended for any first-time nonemergent concomitant *nonmitral operation* to restore sinus rhythm and improve long-term outcomes.	I	B-NR
Recommendations for concomitant left atrial appendage management:					
It is reasonable to perform left atrial appendage excision or exclusion in conjunction with surgical ablation for atrial fibrillation for longitudinal thromboembolic morbidity prevention.	IIa	C	Left atrial appendage obliteration for atrial fibrillation is recommended for all first-time nonemergent cardiac surgery procedures, with or without concomitant surgical ablation, to reduce morbidity from thromboembolic complications.	I	A
At the time of concomitant cardiac operations in patients with atrial fibrillation, it is reasonable to surgically manage the left atrial appendage for longitudinal thromboembolic morbidity prevention.	IIa	C			
Recommendations regarding stand-alone left atrial appendage management:					
			Isolated surgical left atrial appendage obliteration may be considered in patients with longstanding persistent atrial fibrillation, a high stroke risk, and contraindications for or failure of long-term oral anticoagulation.	IIb	B-NR
Recommendations for patients being considered for transcatheter valve therapies:					
			For patients with symptomatic valve disease and atrial fibrillation, who are deemed of low to intermediate surgical risk, surgical valve repair or replacement with concomitant surgical ablation and left atrial appendage occlusion is reasonable over isolated transcatheter valve repair or replacement alone to restore sinus rhythm and improve long-term outcomes.	IIa	B-NR

n; LOE, level of evidence; STS, The Society of Thoracic Surgeons.

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TABLE 1 The Society of Thoracic Surgeons 2023 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation Recommendations

Recommendations	COR	LOE
Recommendations for mitral valve operations		
Surgical ablation for atrial fibrillation is recommended for first-time nonemergent concomitant *mitral operations* to restore sinus rhythm and improve long-term outcomes.	I	A
Recommendations for operations other than mitral valve surgery		
Surgical ablation for atrial fibrillation is recommended for any first-time nonemergent concomitant *nonmitral operation* to restore sinus rhythm and improve long-term outcomes.	I	B-NR
Recommendations regarding stand-alone surgical ablation		
Surgical ablation for symptomatic atrial fibrillation in the absence of structural heart disease refractory to class I/III antiarrhythmic drugs, catheter-based therapy, or both, is reasonable as a primary stand-alone procedure to restore sinus rhythm.	IIa	B-NR
Surgical ablation for symptomatic persistent or longstanding persistent atrial fibrillation in the absence of structural heart disease is reasonable as a stand-alone procedure using the Cox maze III/IV lesion set as the preferred procedure.	IIa	B-NR
Surgical ablation for symptomatic atrial fibrillation in the setting of left atrial enlargement (≥4.5 cm) or more than moderate mitral regurgitation by pulmonary vein isolation alone is not recommended.	III	C
Recommendations for concomitant left atrial appendage management		
Left atrial appendage obliteration for atrial fibrillation is recommended for all first-time nonemergent cardiac surgery procedures, with or without concomitant surgical ablation, to reduce morbidity from thromboembolic complications.	I	A
Recommendations regarding stand-alone left atrial appendage management		
Isolated surgical left atrial appendage obliteration may be considered in patients with longstanding persistent atrial fibrillation, a high stroke risk, and contraindications for or failure of long-term oral anticoagulation.	IIb	B-NR
Recommendations for patients being considered for transcatheter valve therapies		
For patients with symptomatic valve disease and atrial fibrillation, who are deemed of low to intermediate surgical risk, surgical valve repair or replacement with concomitant surgical ablation and left atrial appendage occlusion is reasonable over isolated transcatheter valve repair or replacement alone to restore sinus rhythm and improve long-term outcomes.	IIa	B-NR
Recommendations for all patients with atrial fibrillation		
Multidisciplinary heart team assessment and treatment planning as well as long-term follow-up using periodic continuous electrocardiographic monitoring for rhythm assessment, are recommended to optimize patient outcomes.	I	C

ecommendation; LOE, level of evidence.

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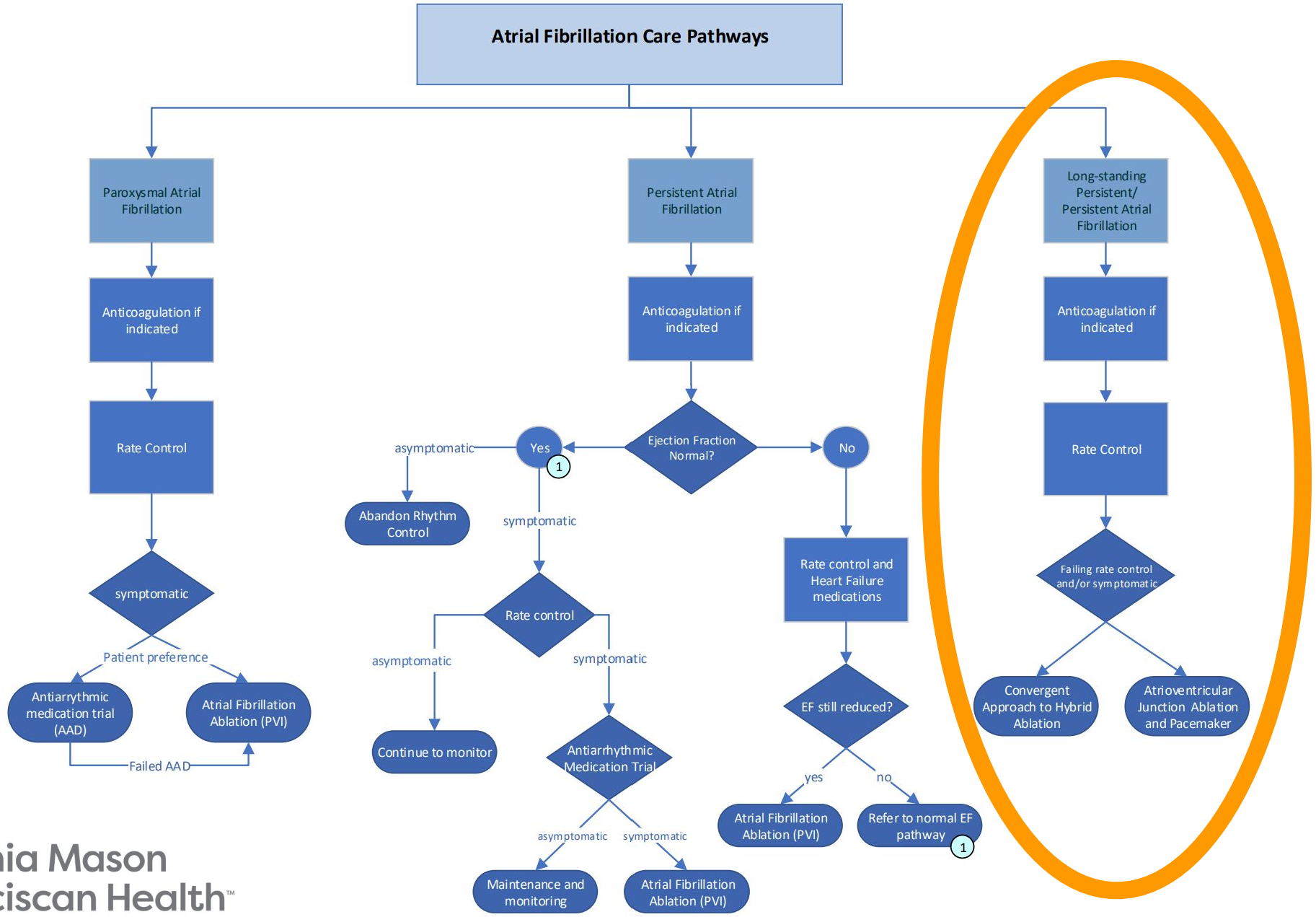

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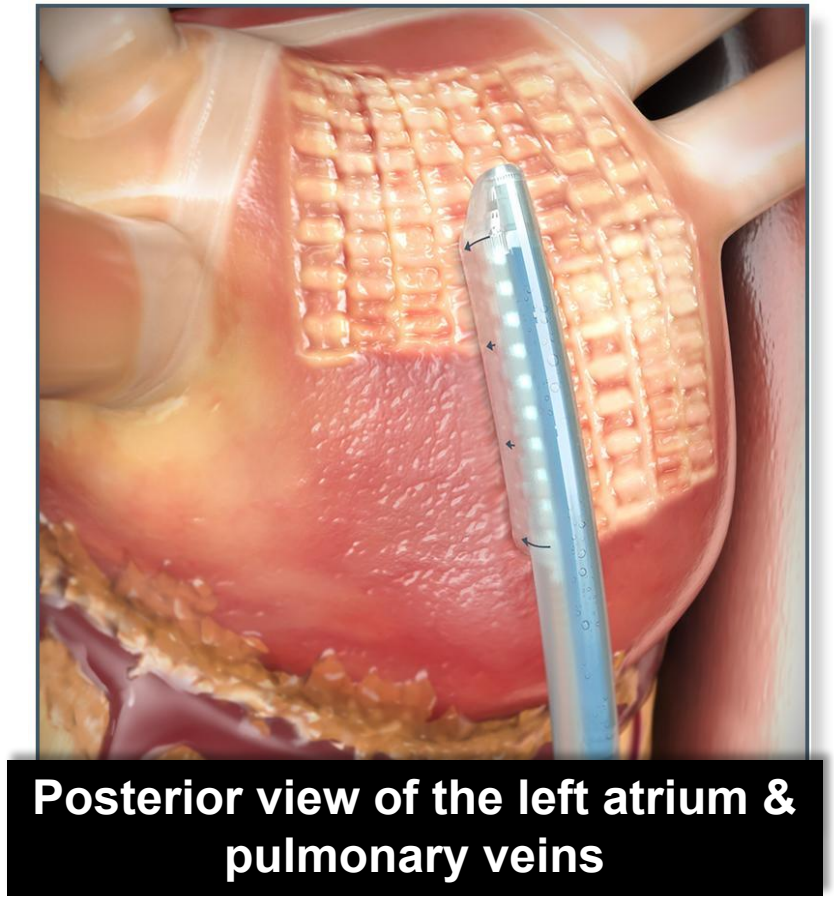
Hybrid AF™ Convergent Therapy

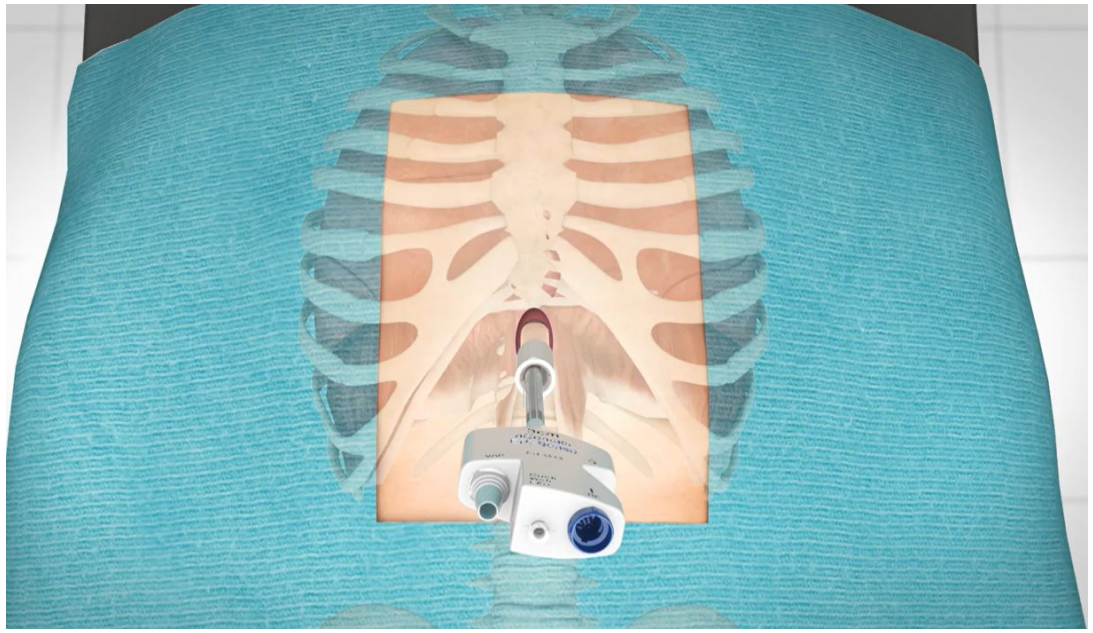
Combines minimally invasive techniques and technologies of EP and CT[31]

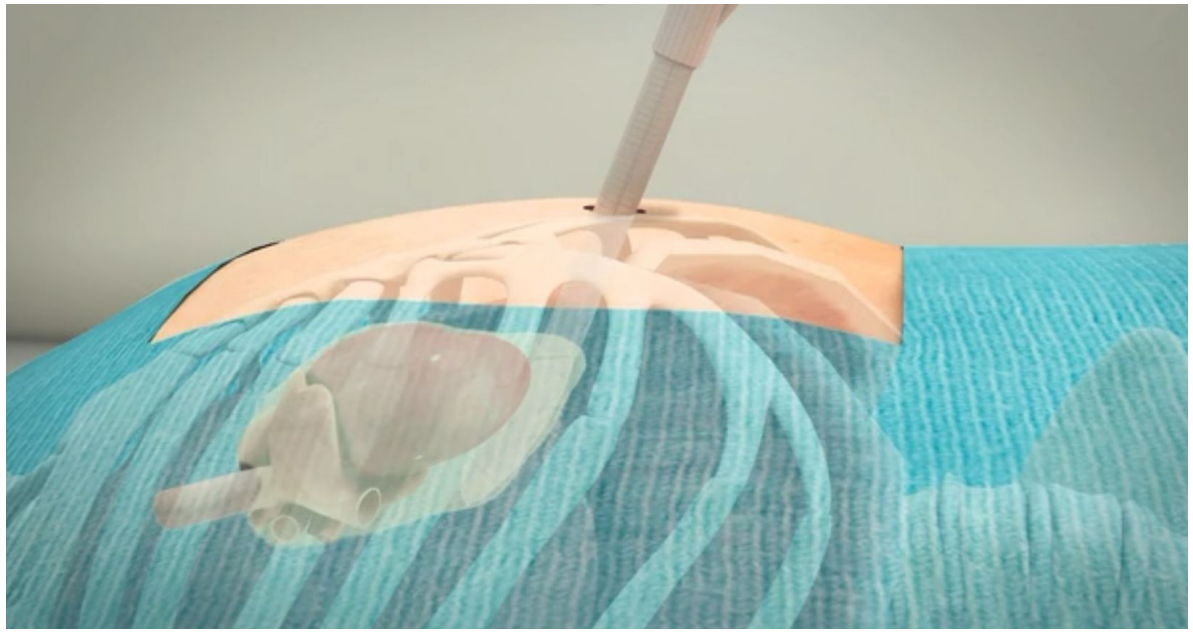


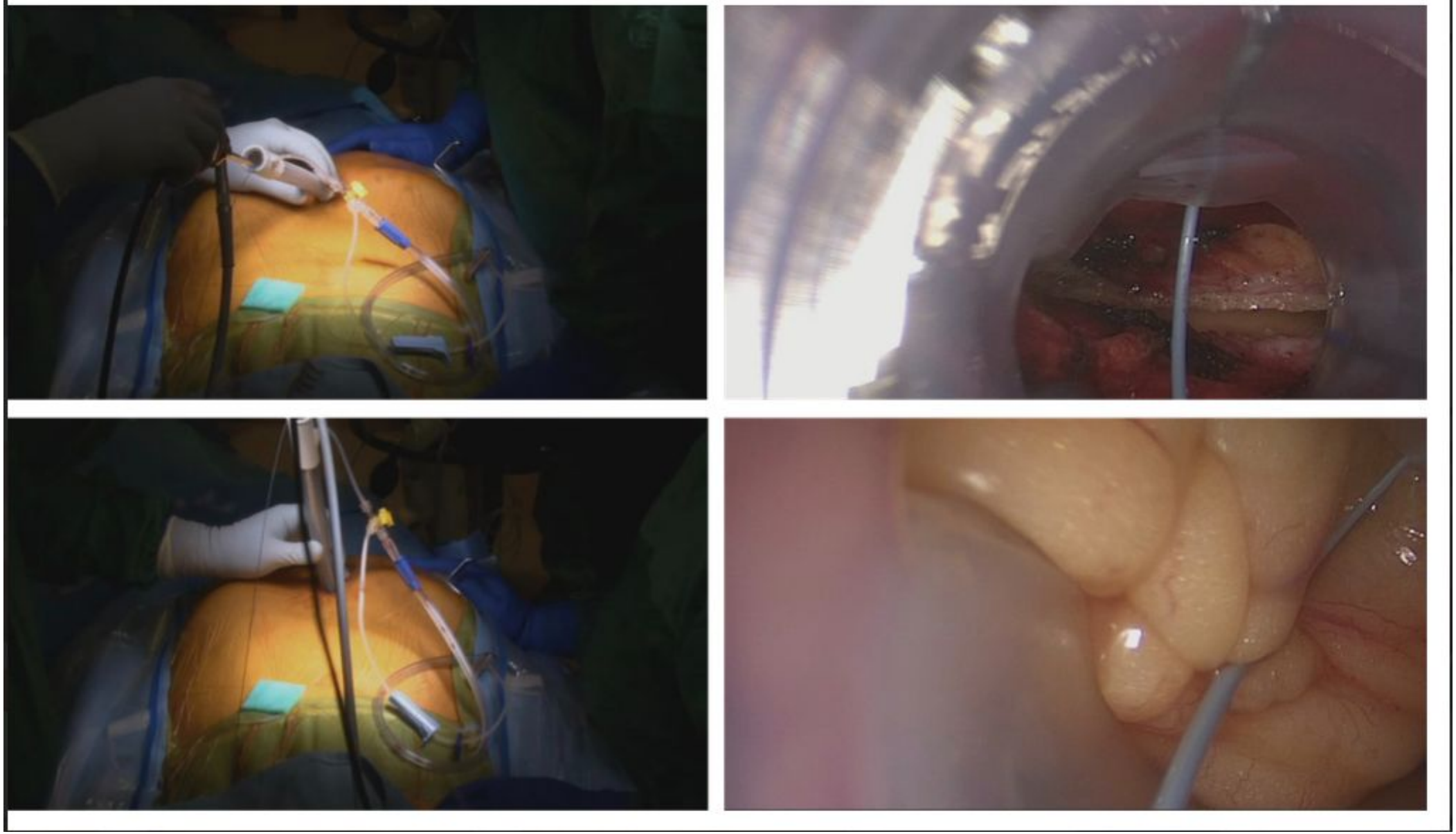
Posterior view of the left atrium & pulmonary veins

- Epicardial Ablation Procedure:
  - CT surgeon complements PVI by providing a comprehensive posterior wall ablation
  - Minimally invasive subxiphoid access
  - RF energy applied away from esophagus
  - Direct endoscopic visualization
- Endocardial Ablation Procedure:
  - EP procedure done same day or staged
  - EP maps identify regions requiring additional ablation
  - Completes the lesion set and the Hybrid AF procedure with pulmonary vein isolation

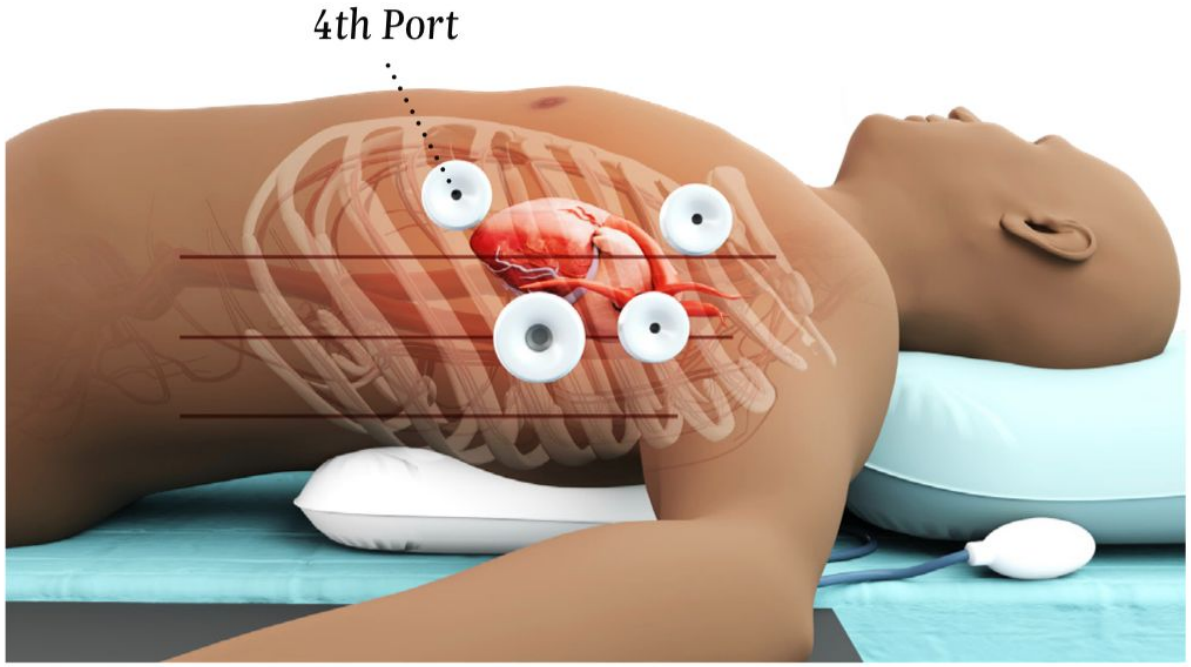
Hybrid AF Convergent Therapy

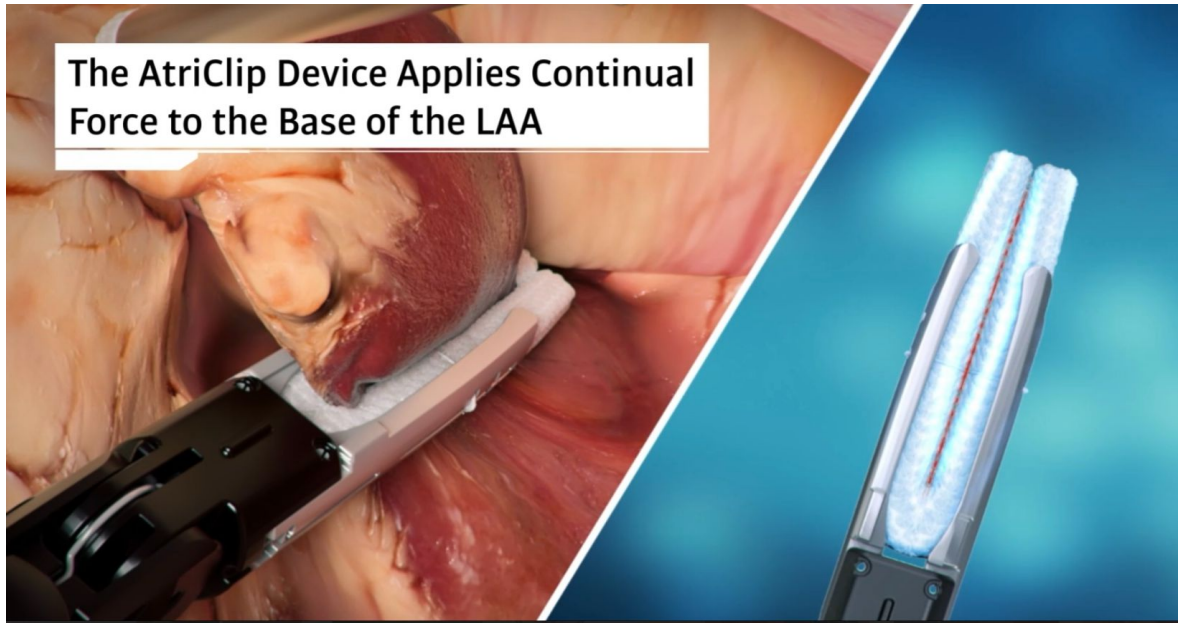






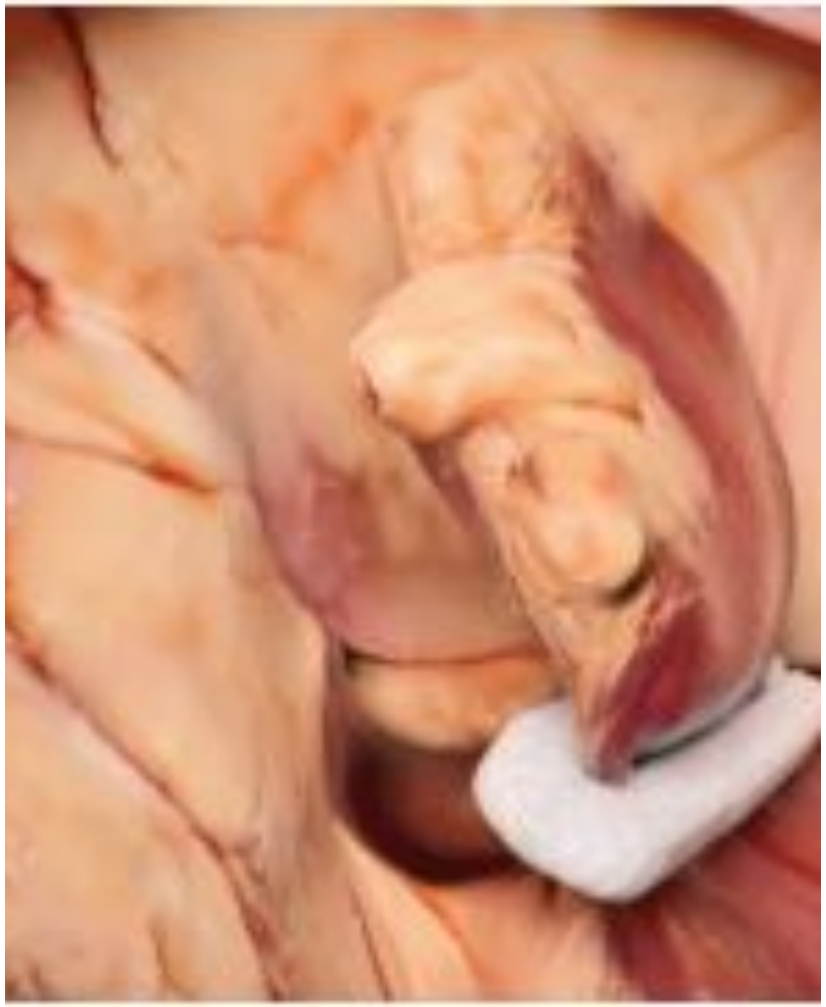

HR= 95 bpm
630 ms
BP= -34/-35/-35 mmHg





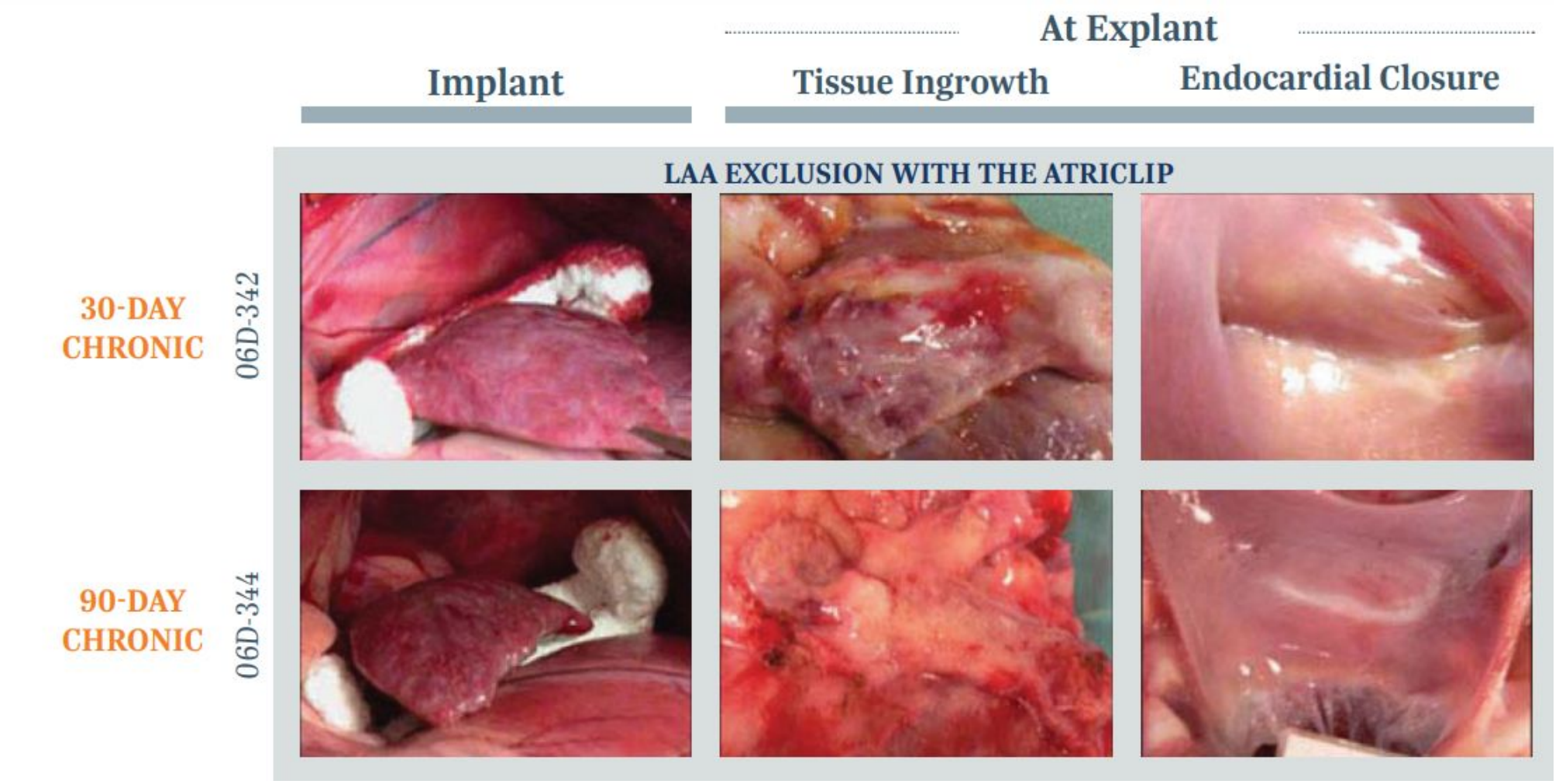
Left Atrial Appendage Management (LAAM)

Mechanisms of LAA exclusion and subsequent electrical isolation



- The epicardial application of the AtriClip device excludes vascularization to the LAA
- Ischemic injury to the LAA ceases all electrical activity within minutes
- The AtriClip continues to exclude throughout tissue changes that occur as the tissue becomes necrosed
- This continuous closing force maintains LAA exclusion
- Parallel closing bars along the long axis of the LAA ostia appose the tissue without folds that can leave residual flow

LAA Exclusion At Explant



Patient Selection

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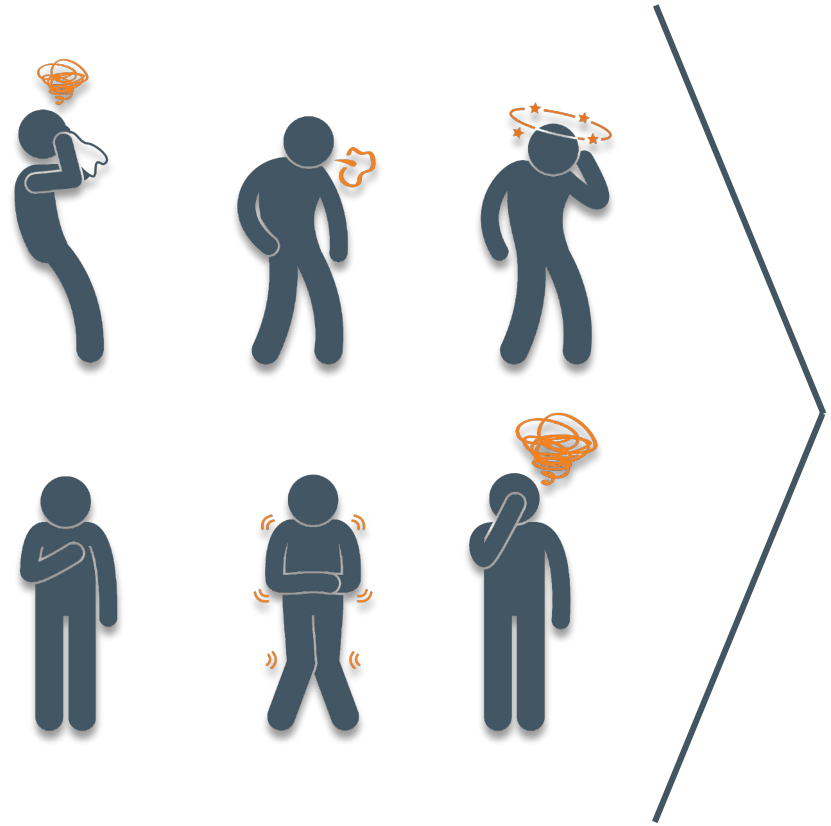
AF Symptoms

Symptoms of Advanced AF Can Be Different[14,15]



Advanced AF Symptoms:

- Shortness of breath
- Dizziness
- Weakness
- Fatigue
- Lowered blood pressure
- Pain or pressure in the chest
- Rapid or irregular heartbeat

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Advanced AF Patients

Most Prevalent and Most Difficult to Treat AF Population

Patient Selection:[1]

- Intolerant to at least one class I/III antiarrhythmic drug
- Patients in symptomatic AF for more than 12 months
- Left Atrium size up to 6 cm
- No limits on the duration of AF

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

SMMC Convergent Experience

- 31 cases to date (One aborted secondary to complete heart block)
- 5 in the queue the next two months
- No deaths
- No significant pericarditis or effusion
- Length of stay 2 days, could be shortened to one
- Anti-inflammatory regimen
- Anti-arrhythmic regimen
- Drains discontinued POD#1
- F/U EP ablation in 6-12 weeks
- No sustained periods of AF documented per patient or on serial EKGs,
- no zio or loop insertion yet per EP preference
- Improved QOL survey, and symptom survery

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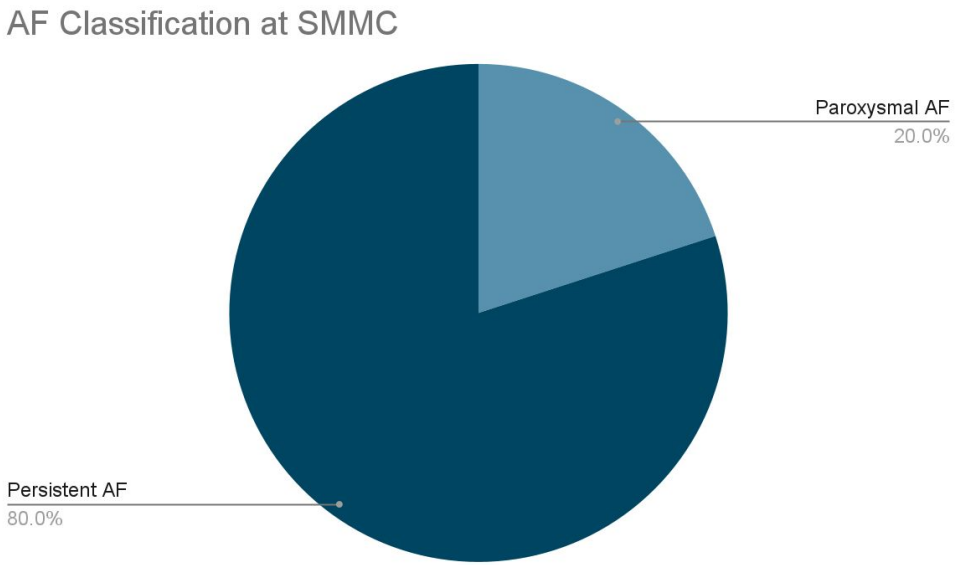
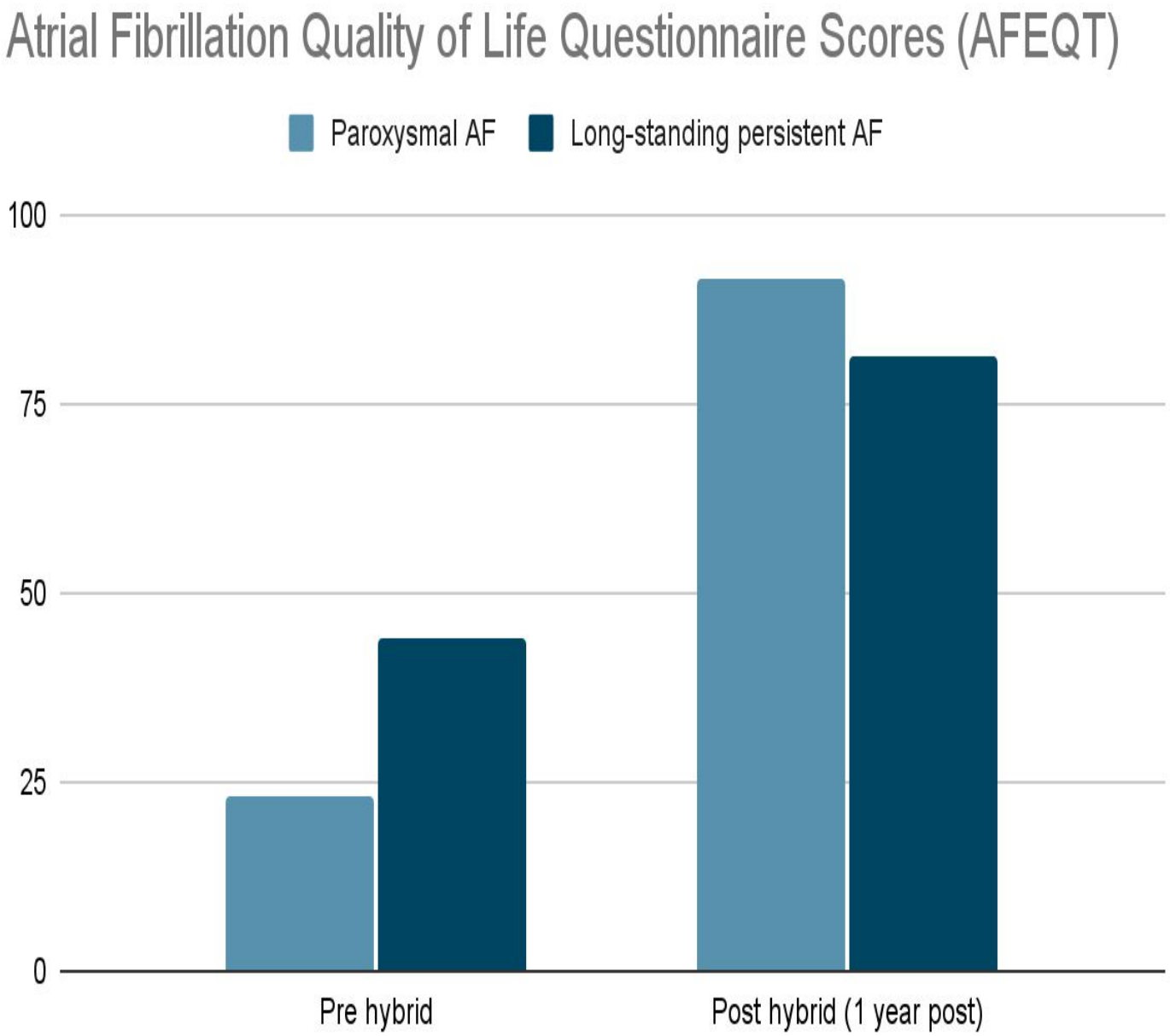
SMMC Outcomes





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Convergent Patient JW 1/17/2023

- 48yo female
- Epicardial 12/9/2022 and clip
- **PVI case date 1/17/2023**
  - PAF and tachy induced cardiomyopathy. Onset at age 34
  - PVI 2016 at Skagit, repeat cryo ablation 2020 at PeaceHealth
  - Sotalol not tolerated in the past
  - AF described as debilitating
  - Moderate to severe MR on echo with EF 20% during hospitalization, repeat echo after HF med titration and rate control showed improvement (mild regurg and EF 38%)
  - S/p convergent hybrid ablation and LAA clip, maintains NSR, off AAD
  - EF normalized, no AF on Zio
  - Improved activity tolerance and no concerns with daily activities

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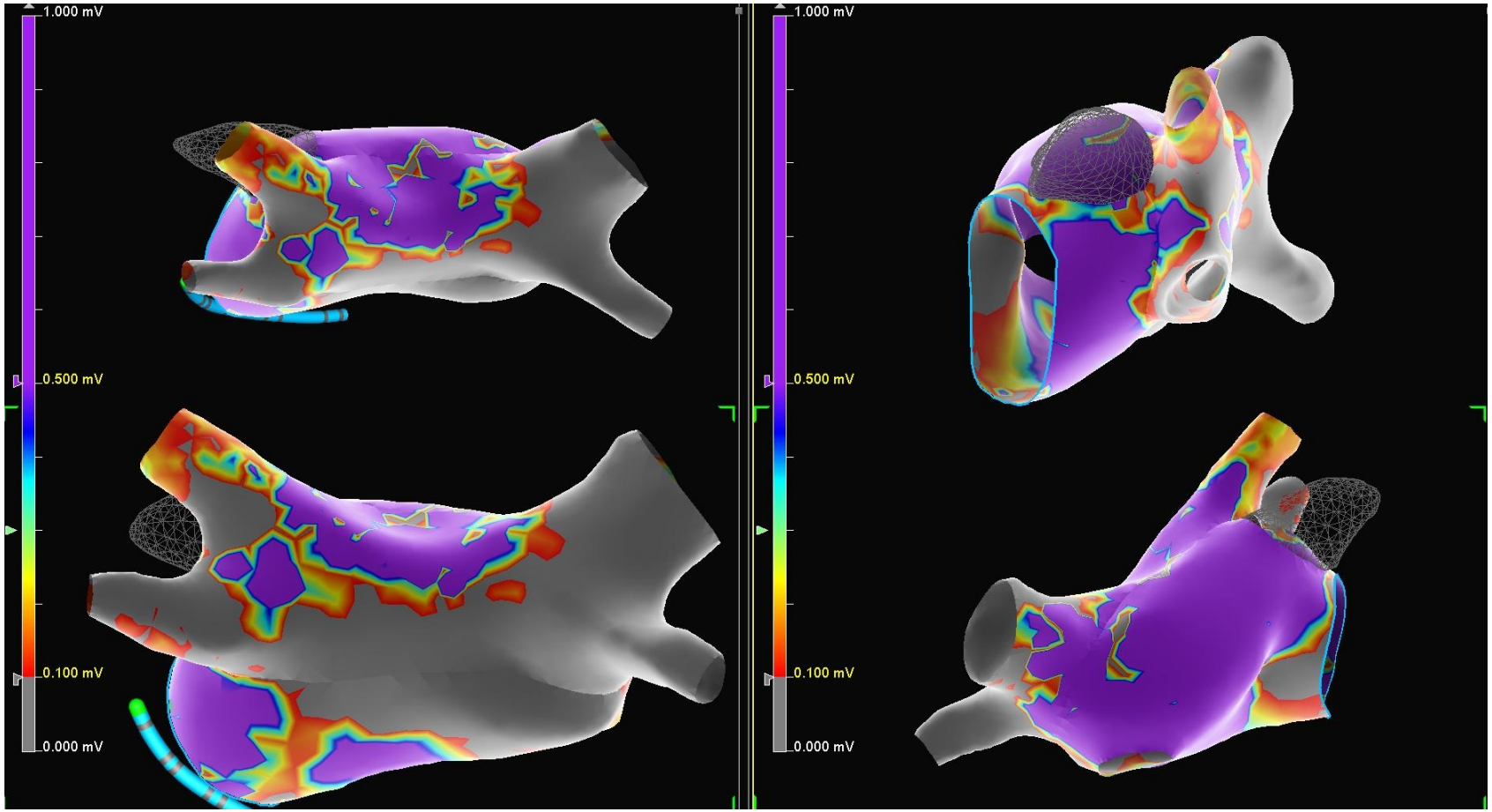
1/17/23



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Convergent Patient RZ 1/17/23

- 86 yo male
- Epicardial 12/9/2022 and clip
- **PVI date 1/17/2023** drug refractory symptomatic atrial fibrillation, 3 previous PVI's
  - preserved LV function
  - on sotalol and warfarin, SSS, high grade AV block sp DC PPM (April, 2017) and new RV lead revision (April, 2019)
  - Plan was for AVJ until hybrid was presented as an option
  - Underwent hybrid ablation and LAA clip
  - No AF noted on device since hybrid ablation
  - More "vim and vigor" since ablation

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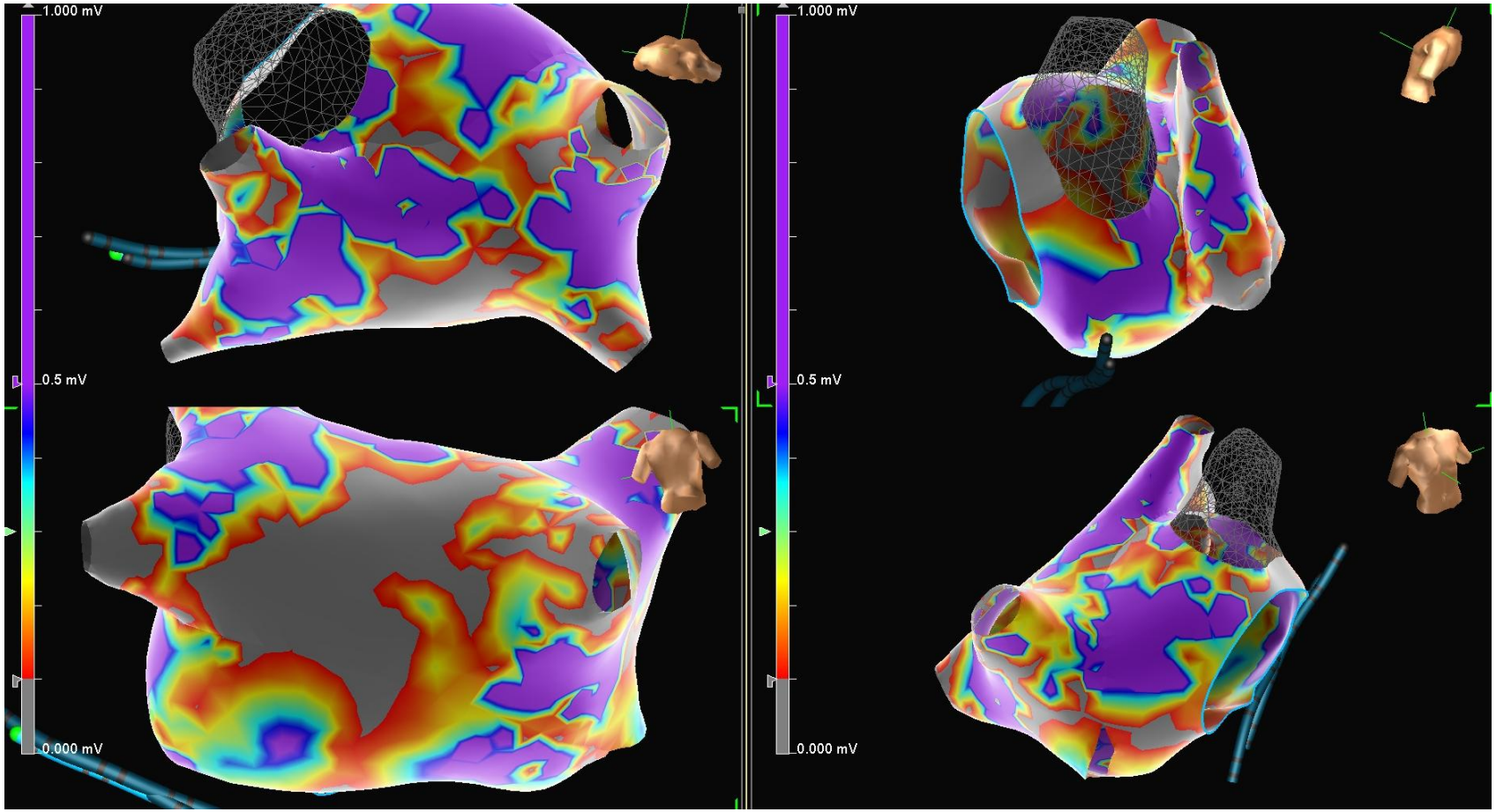
1/17/23



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Convergent Patient VS 1/20/22

- 68 yo male
- Epicardial12/13/2021
- **PVI Case date 01/20/2022** Persistent long standing atrial fibrillation- no previous ablations
  - Accompanying left ventricular systolic dysfunction, nadir ejection fraction < 30,
  - Severe LAE, Nonischem CM
  - Post convergent sinus brady - Zio negative, no AF since phase 2.
  - Physical activity still progressing well
  - now s/p convergent surgery/RFCA and LVEF completely normalized.

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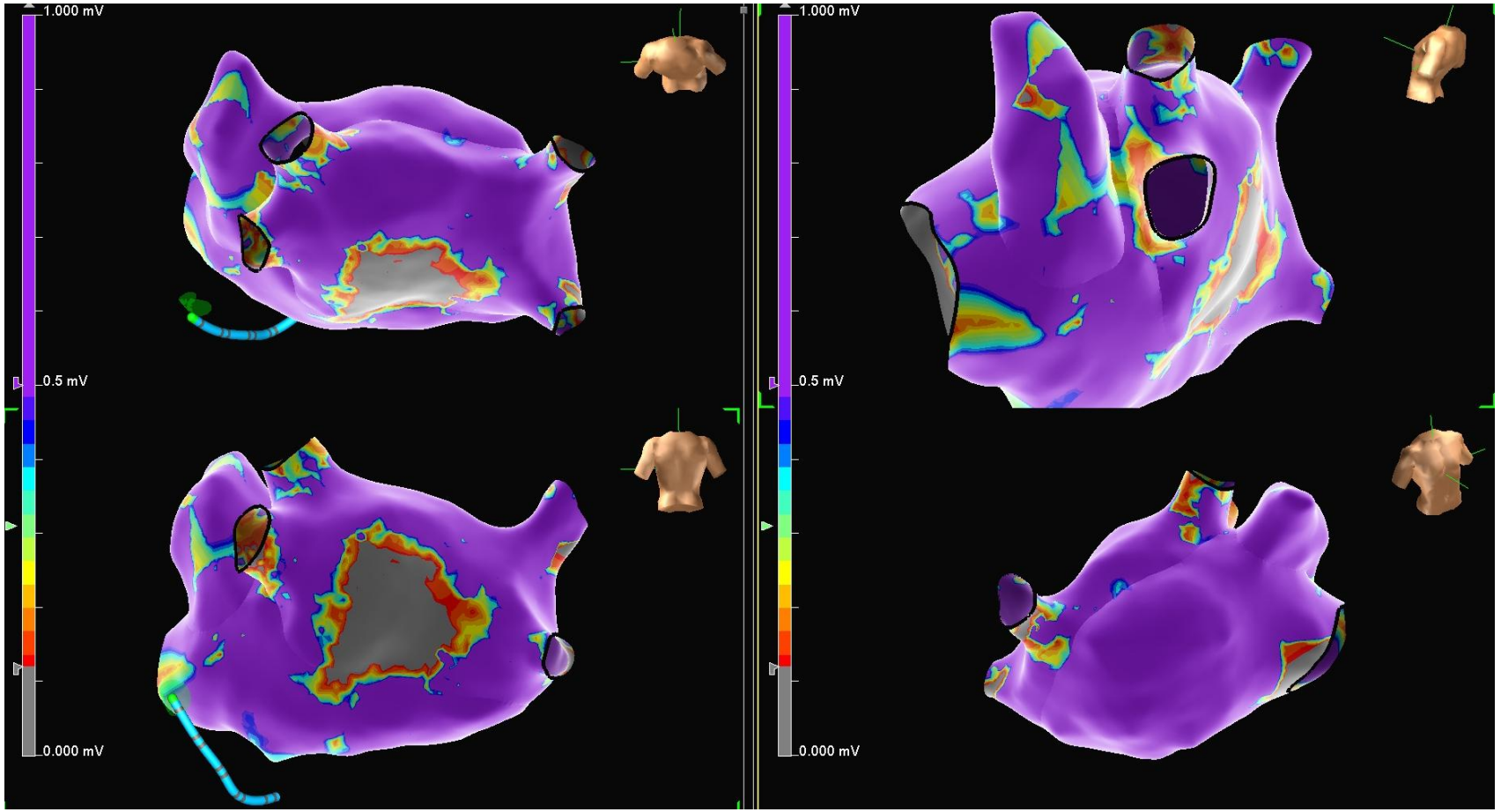
1/20/22



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Advanced AF Patients

Most Prevalent and Most Difficult to Treat AF Population

Patient Selection:[1]

- Intolerant to at least one class I/III antiarrhythmic drug
- Patients in symptomatic AF for more than 12 months
- Left Atrium size up to 6 cm
- No limits on the duration of AF

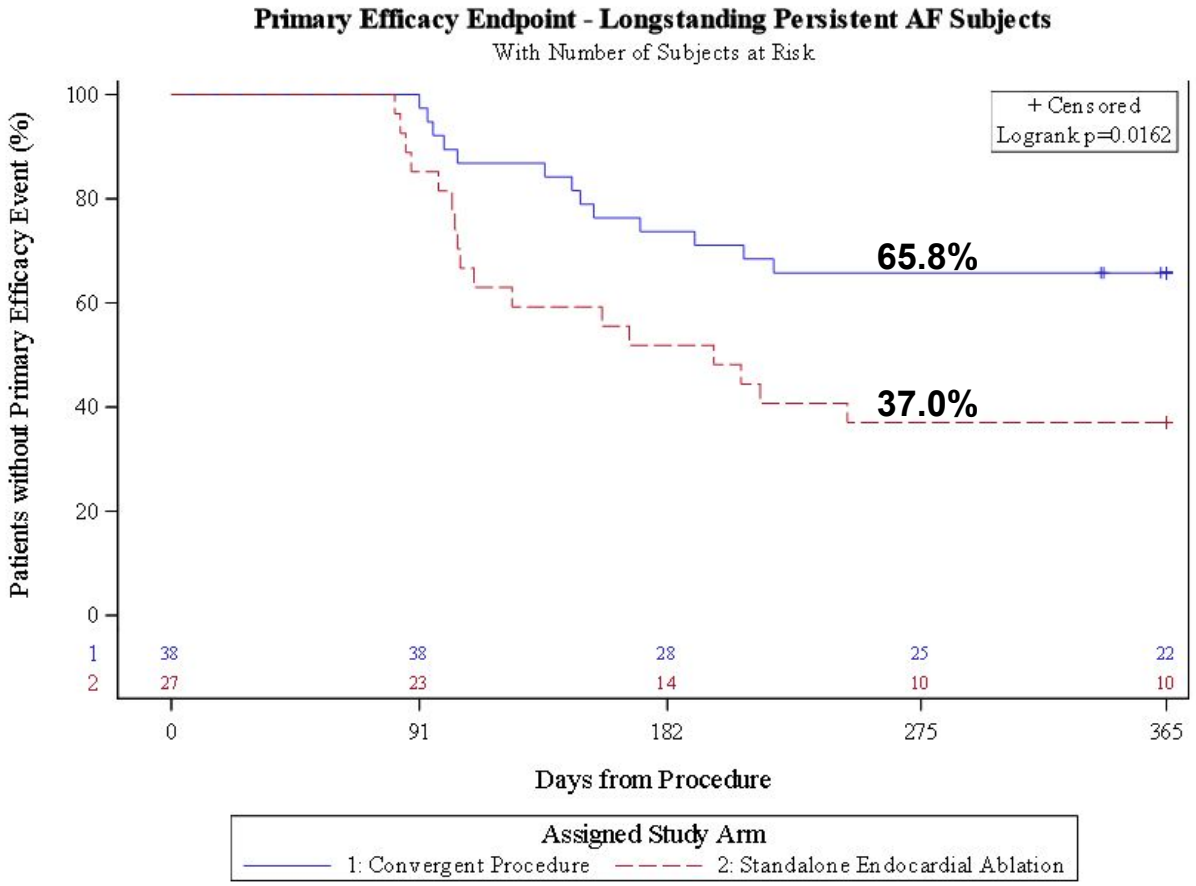
[1]IFU for EPi-Sense® Guided Coagulation System Data: PMA# P200002

Converge Trial & Data

Reliable Outcomes for Hybrid AF Convergent Therapy (Multi-Center)

- Freedom from atrial arrhythmias at 1 yr. or later (+/- AADs):
  - **75%** (95% CI 66.0%- 83.9%; n=805; 14 studies)[32]
- Freedom from atrial arrhythmia at 1 yr. or later (off AADs):
  - **64.9%** (95% CI 54.7%-75.1%; n=494; 8 studies)[32]
- AF Burden rate:
  - At 1 year, **94%** of patients had ≤5% AF burden, and mean AF burden was 5% among those who had recurrence[33]
  - With mean follow-up of 19 months, **88%** of patients had ≤5% AF burden, 80% had ≤1% AF burden, mean AF burden was 8.5% at last follow-up[34]

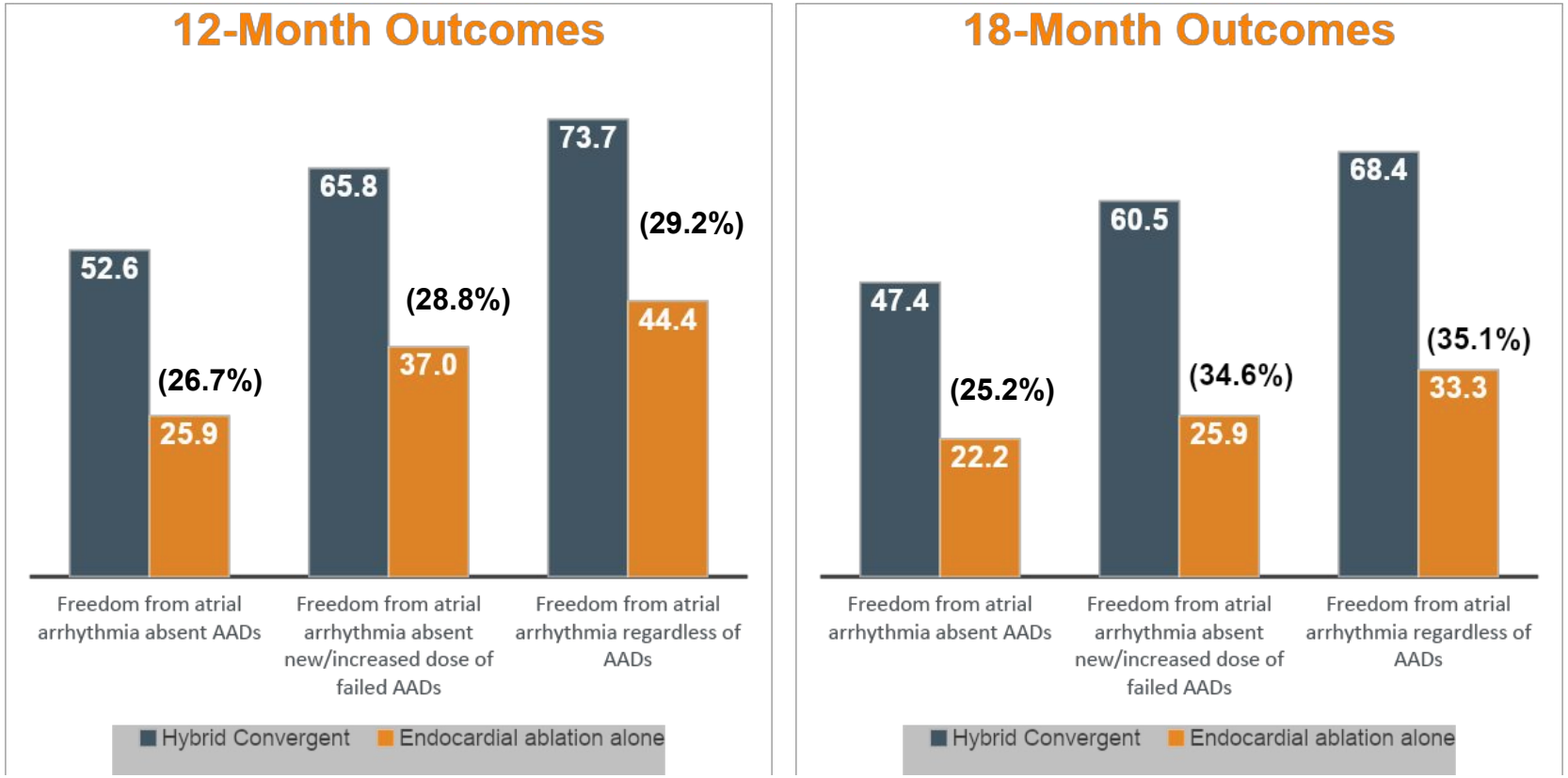
Results of CONVERGE Trial[35]
Primary effectiveness through 12 months



The absolute difference of 28.8% (78% improvement) is higher with the Hybrid AF procedure

Source: David DeLurgio, MD

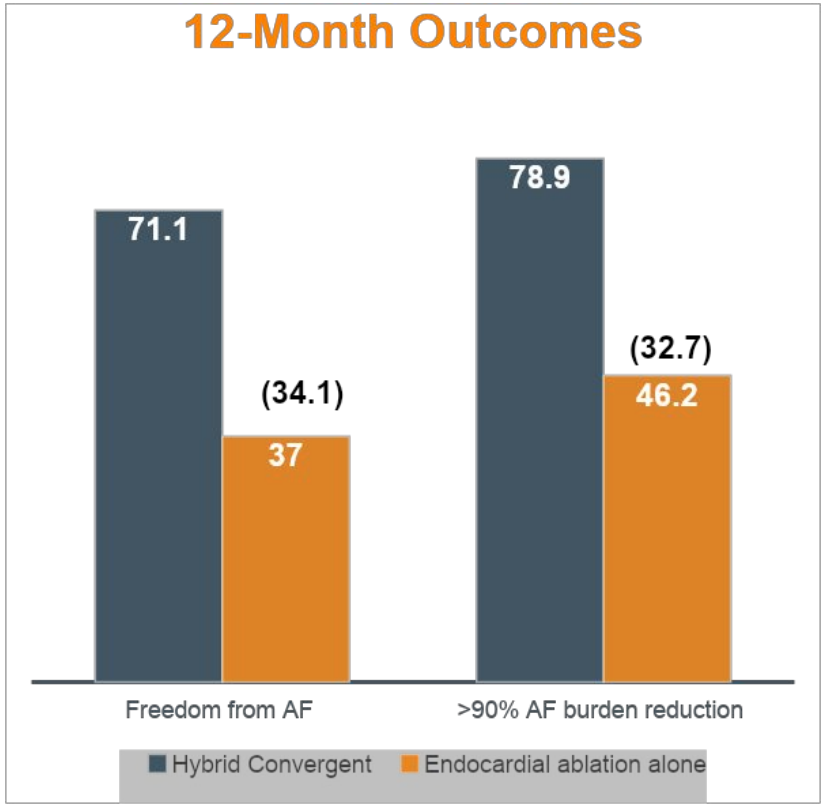
Hybrid AF CONVERGE IDE Trial: Outcomes[35,36] Long-Standing Persistent

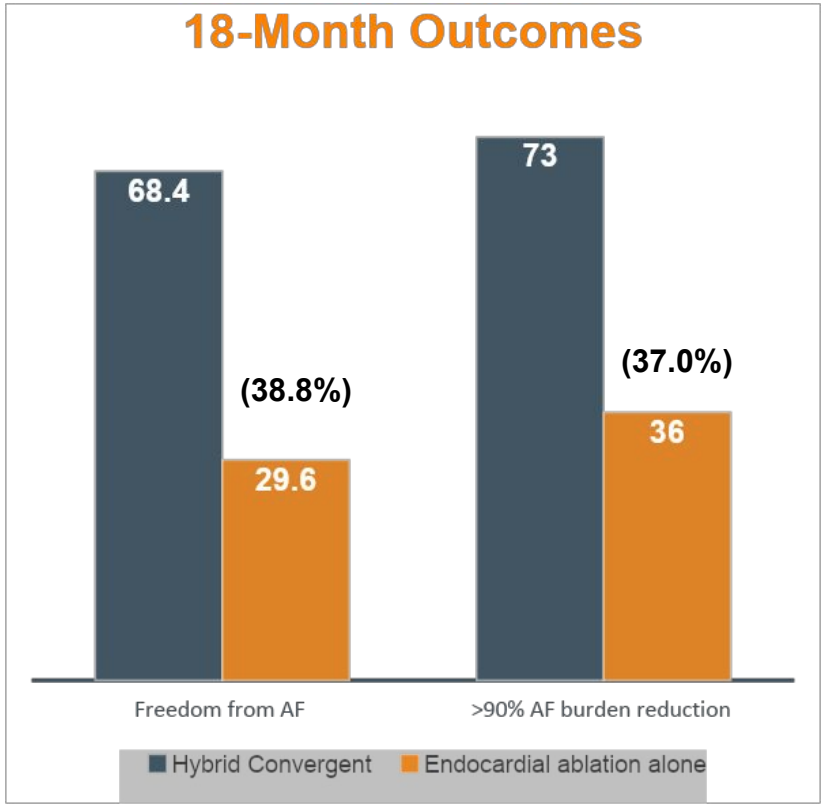


Freedom from atrial arrhythmia with and/or without AADs was notably higher with Hybrid AF Convergent vs endocardial ablation alone, and sustained through 18 months (7-day Holter)

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

Hybrid AF CONVERGE IDE Trial: Outcomes[35,36] Long-Standing Persistent



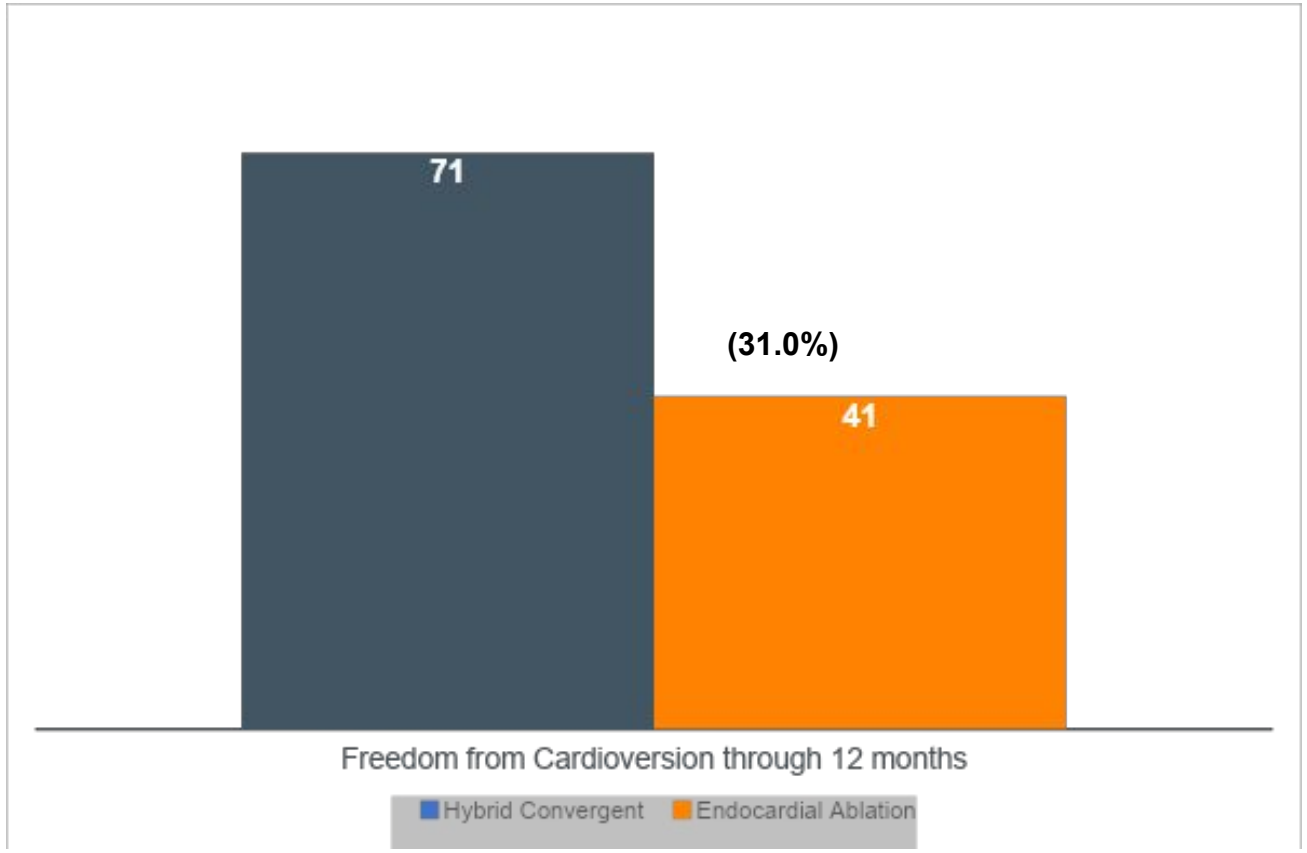


Freedom from AF and ≥90% reduction in AF burden was notably higher with Hybrid AF Convergent vs endocardial ablation alone, and sustained through 18 months (7-day Holter)

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

Hybrid AF CONVERGE IDE Trial: Outcomes[35,36] Long-Standing Persistent

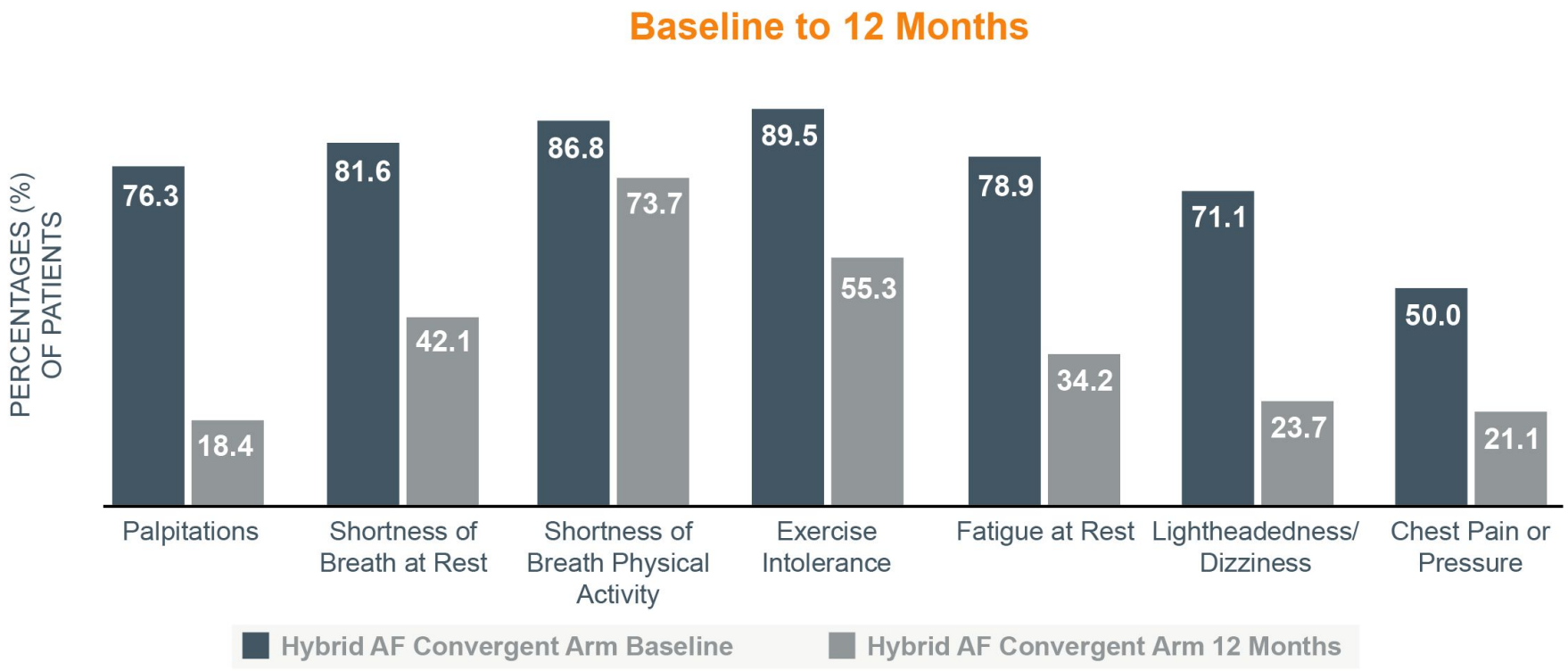
A total of 71% Hybrid Convergent patients vs 41% endocardial ablation patients had freedom from cardioversion through 12 months



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

Hybrid AF CONVERGE IDE Trial: Outcomes[35,36]

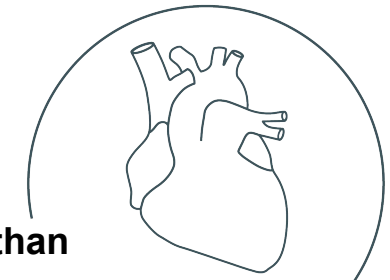
Hybrid AF Convergent Arm AF Symptom Reduction Baseline to 12 Months



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

Hybrid AF CONVERGE IDE Trial: Outcomes[35]

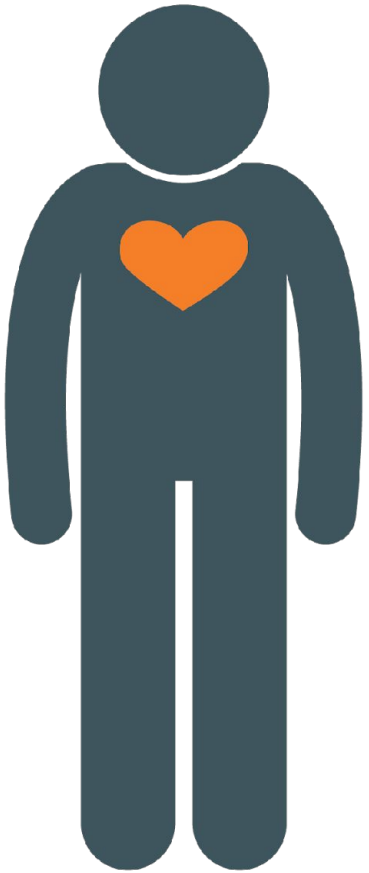
Based on 7-day continuous rhythm monitoring at 18 months post procedure

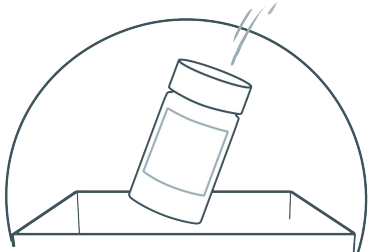


More than

2x AS EFFECTIVE AT STOPPING AA

(vs endocardial RF ablation alone)

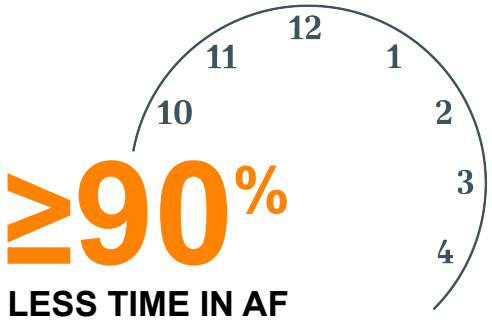




Patients are

2x MORE LIKELY TO NO LONGER NEED AF MEDICATION

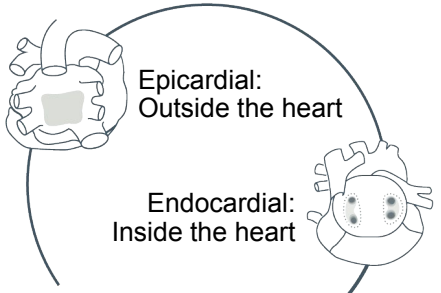
(vs endocardial RF ablation alone)



≥90%

LESS TIME IN AF

for most patients at 1 year



2

TRIGGER AREAS TARGETED

where atrial fibrillation begins

People in the Hybrid AF arm report feeling better, both physically and emotionally[36].
Procedure is safe and effective.

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

Hybrid AF CONVERGE IDE: Outcomes[2,3] Primary Safety Data Summary

7 DAYS

Not Pre-Specified by Protocol in Line with Endocardial Studies

2.9%

30 DAYS

Pre-Specified CONVERGE Protocol

7.8%

CONVERGE Safety Events (Full Cohort):

No Deaths | No Cardiac Perforation | No AE Fistula

Safety Events:

- 1 Stroke (slightly slower left facial movement, did not have debilitating effect)
- 1 Phrenic nerve injury (PNI), resolved
- 1 Bleed
- 1 Bleed with late pericardial effusion
- 1 Transient ischemic attack (TIA)
- 4 cardiac tamponade

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

Vass’s AFib Journey

- https://www.dropbox.com/s/29relilpoi9lzjq/AtriCure_PatientStory-Vass-Seattle_v4.mp4?dl=0