

Innovative Treatments for Atrial Fibrillation

Maria Anderson, MD

Oussama Lawand, MD, FHRS

Srini Iyengar, MD

Boulder Heart

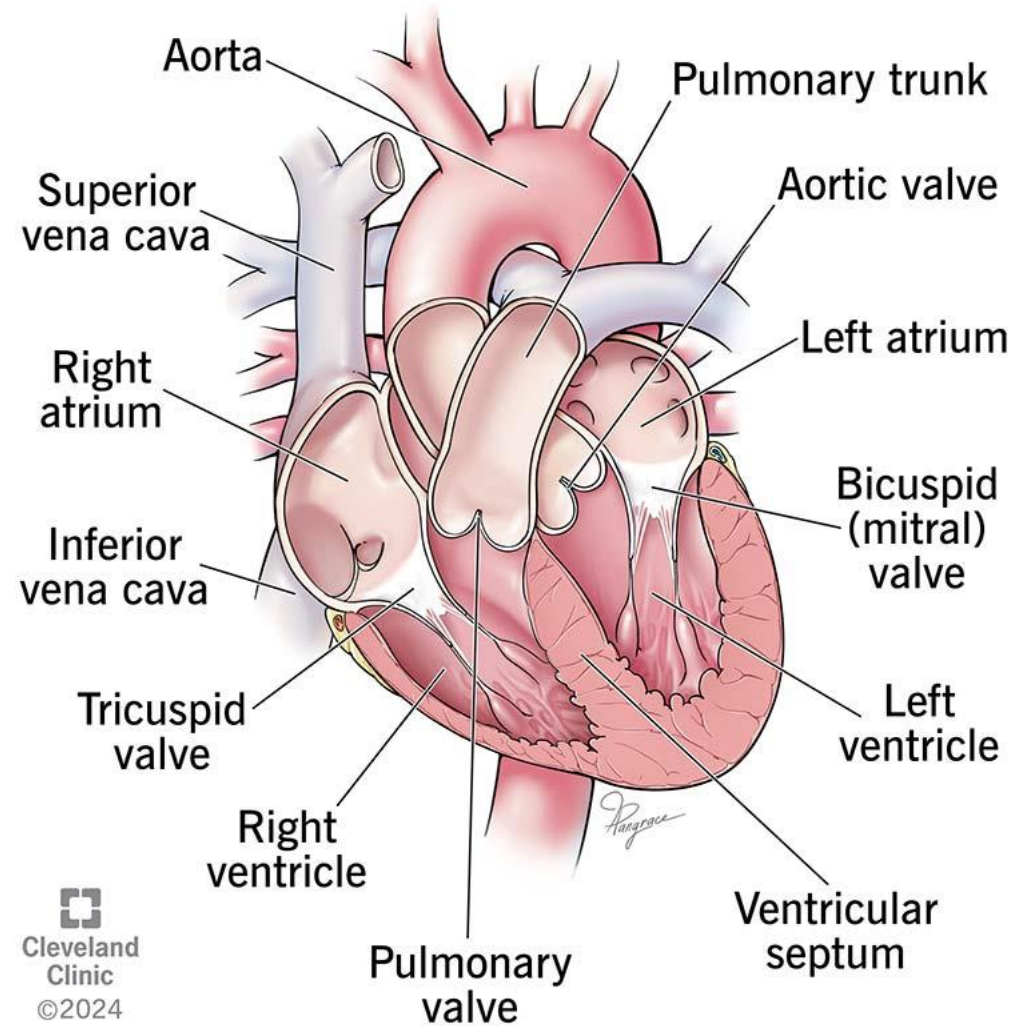
720-453-2822

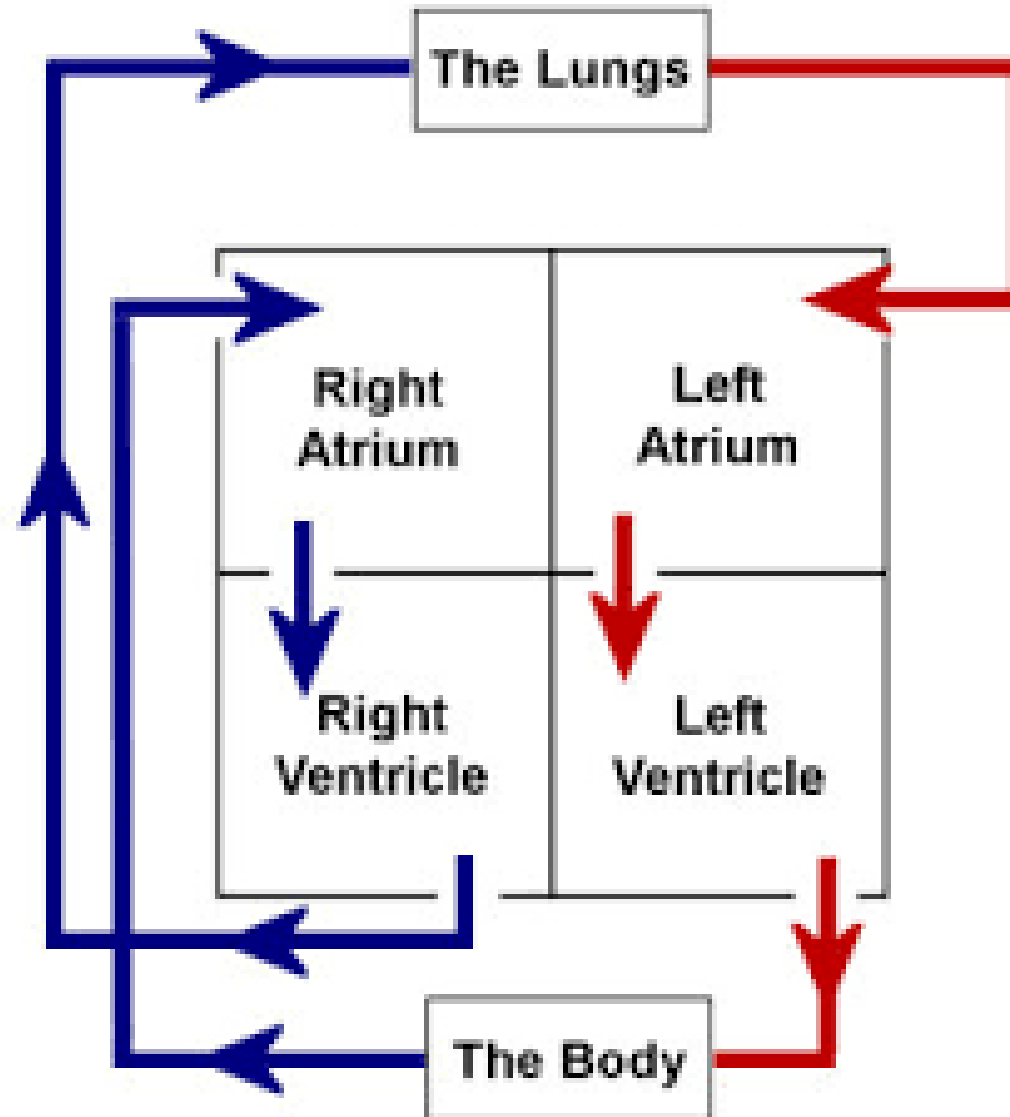
Atrial Fibrillation

Maria Anderson, MD
Boulder Heart

- What is atrial fibrillation?
- Causes of atrial fibrillation
- Concerns for those with atrial fibrillation
- Treatment options for atrial fibrillation
- Stroke prevention in atrial fibrillation

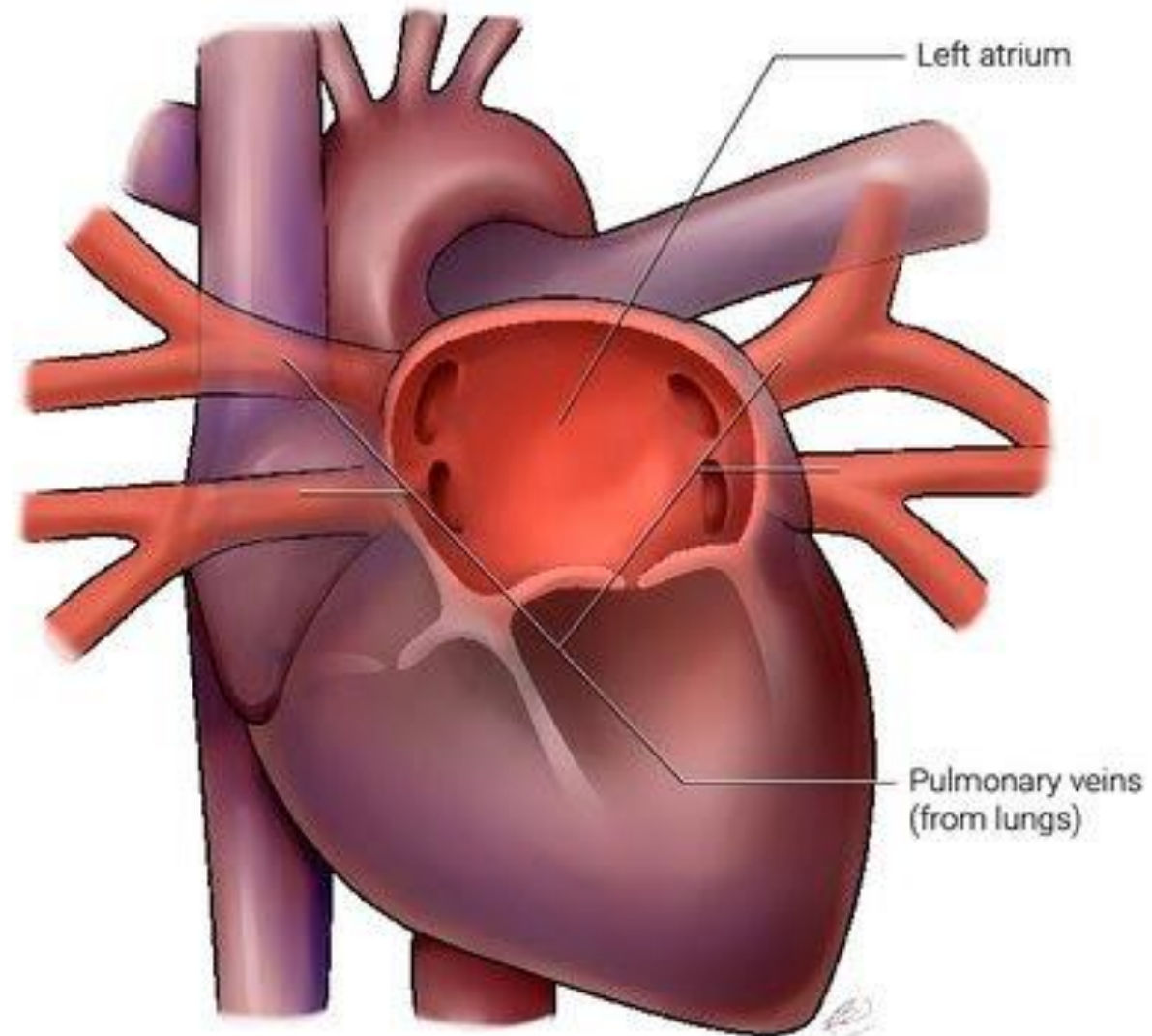
Inside of heart

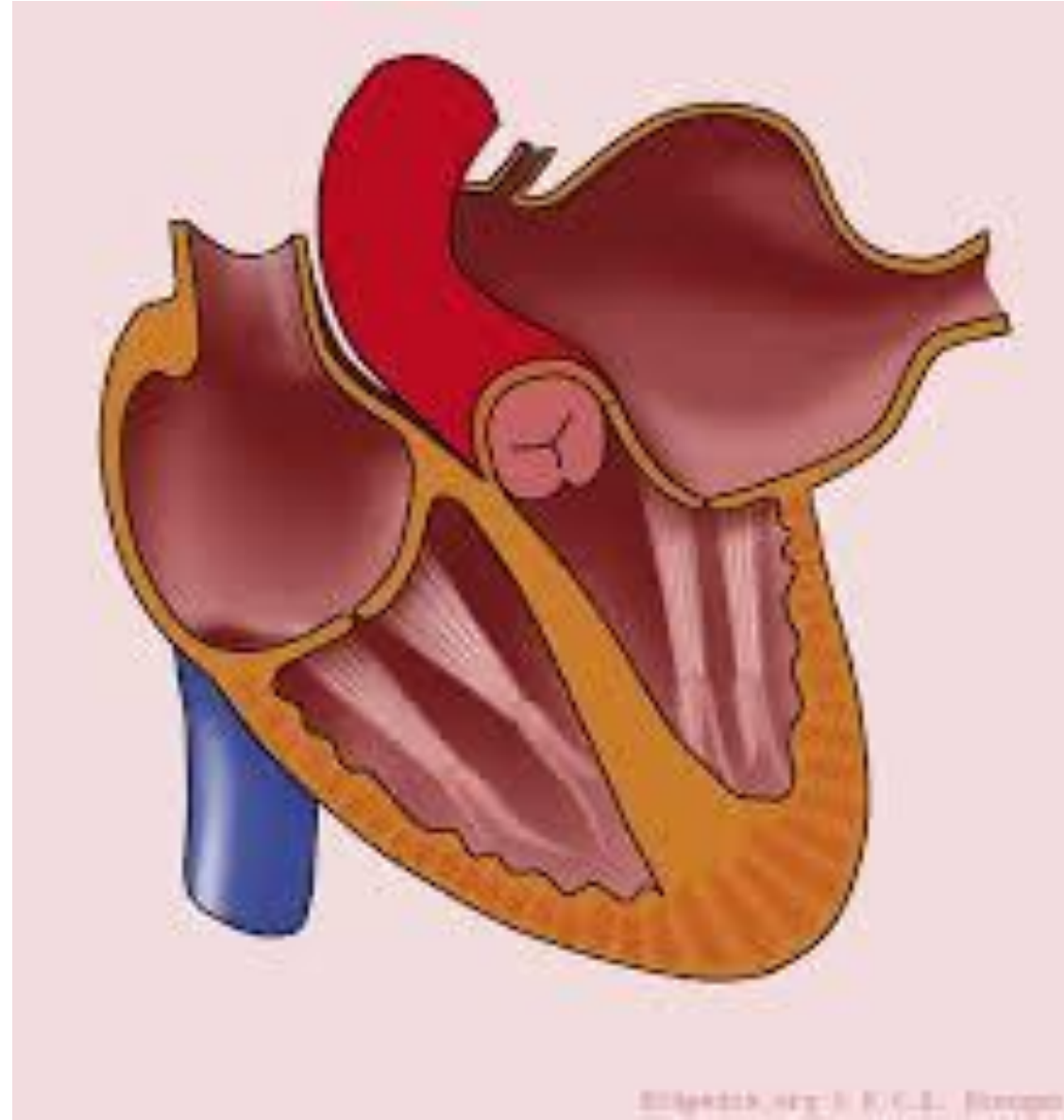




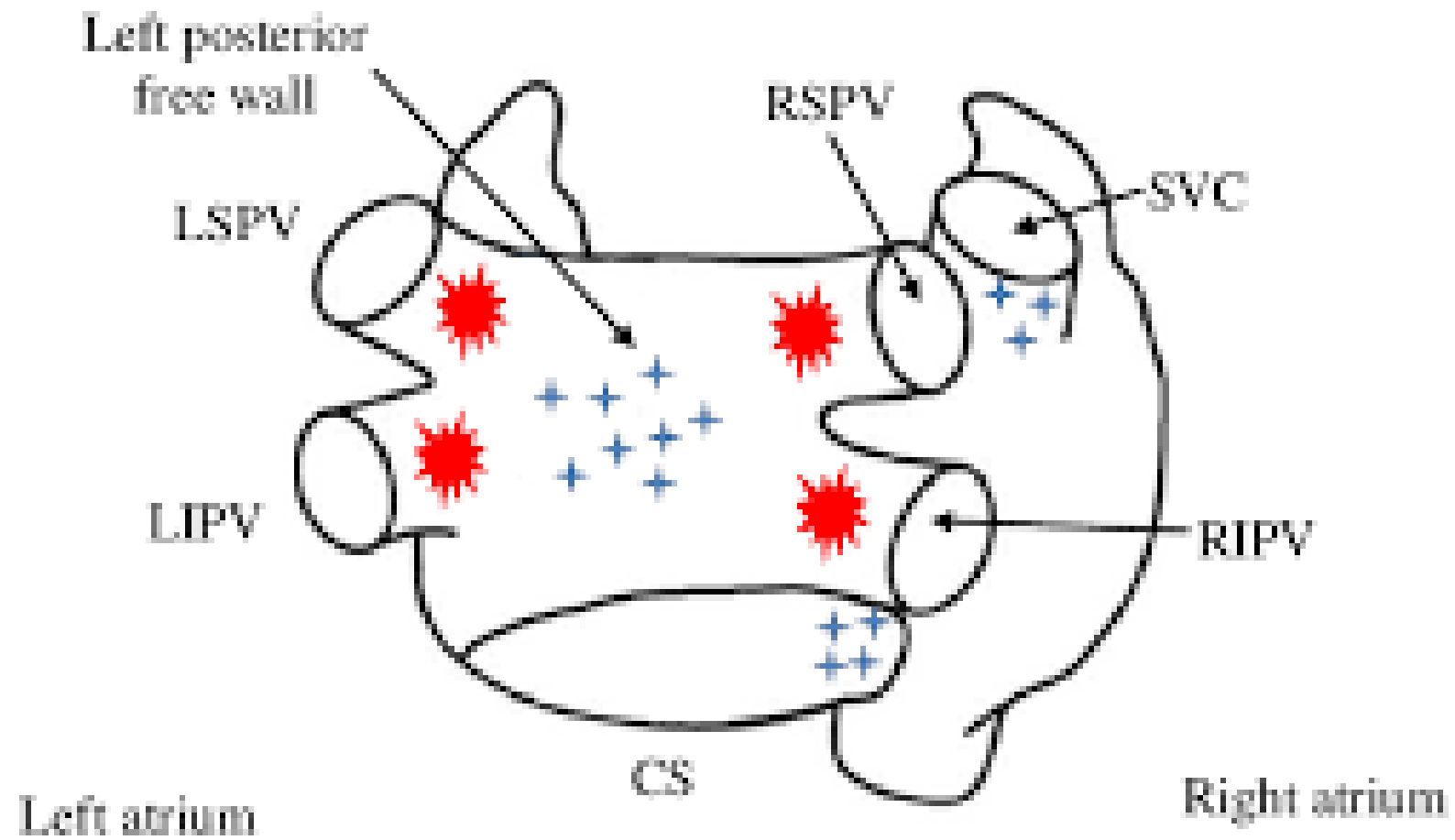
What is Atrial Fibrillation?

- Chaotic electrical activity in the two upper chambers of the heart
- Irregular response in the two ventricles
- Mostly starts in the left atrium and conducts to both atria
- There are triggers for atrial fibrillation within the atria
- The atrium allows atrial fibrillation to perpetuate (substrate)

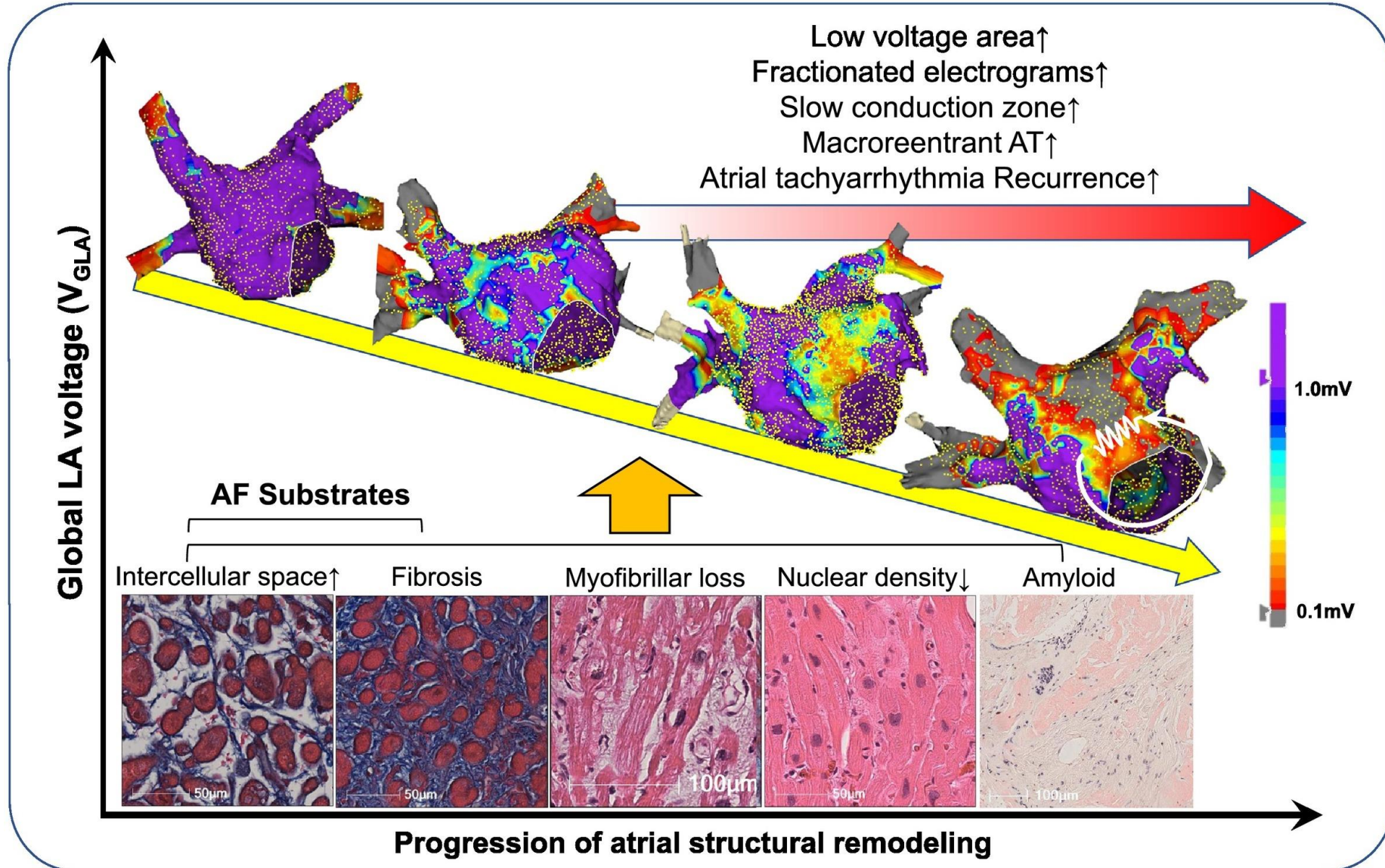




Posterior view



- Atrial fibrillation worsens over time.
- The more atrial fibrillation someone has, the more abnormal the atria get, and the more atrial fibrillation worsens.
- Paroxysmal: early stage, atrial fibrillation comes and goes on its own
- Persistent: middle stage, atrial fibrillation stays until we reset the heart with a cardioversion procedure
- Longstanding persistent: persistent atrial fibrillation for more than six months
- Permanent atrial fibrillation: persistent atrial fibrillation that you and your EP have decided is not likely to ever go back to sinus and you stop trying



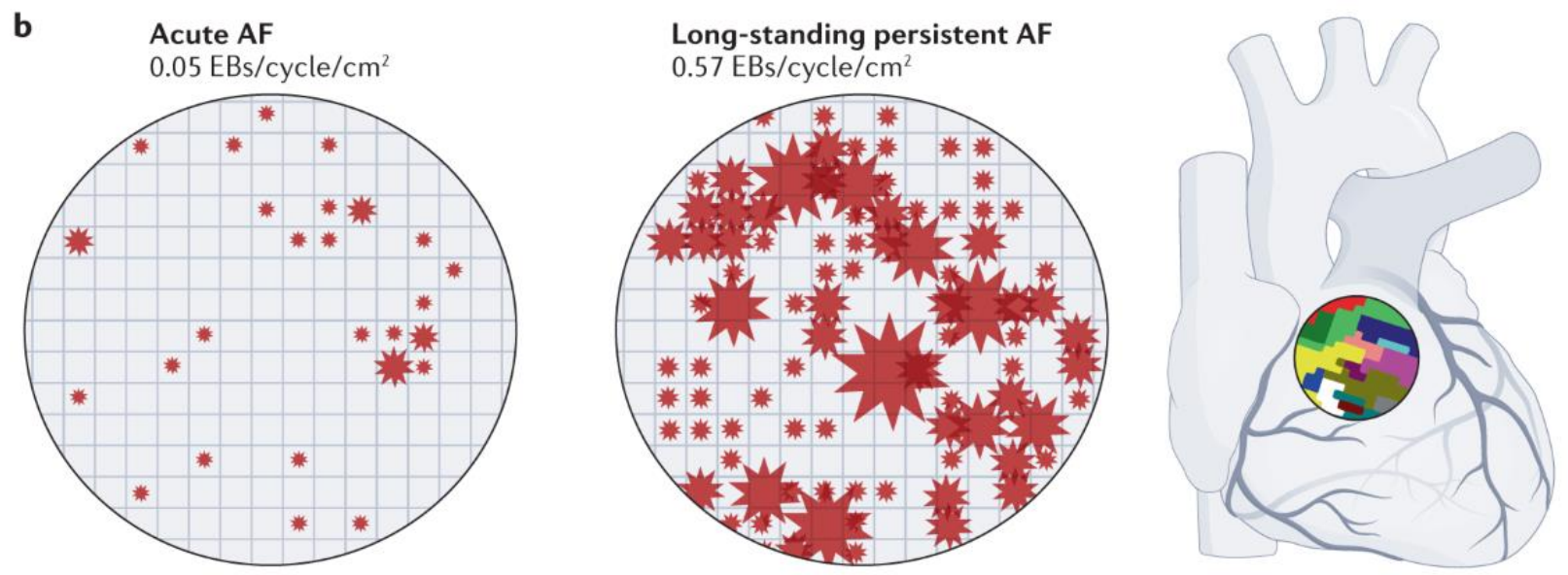
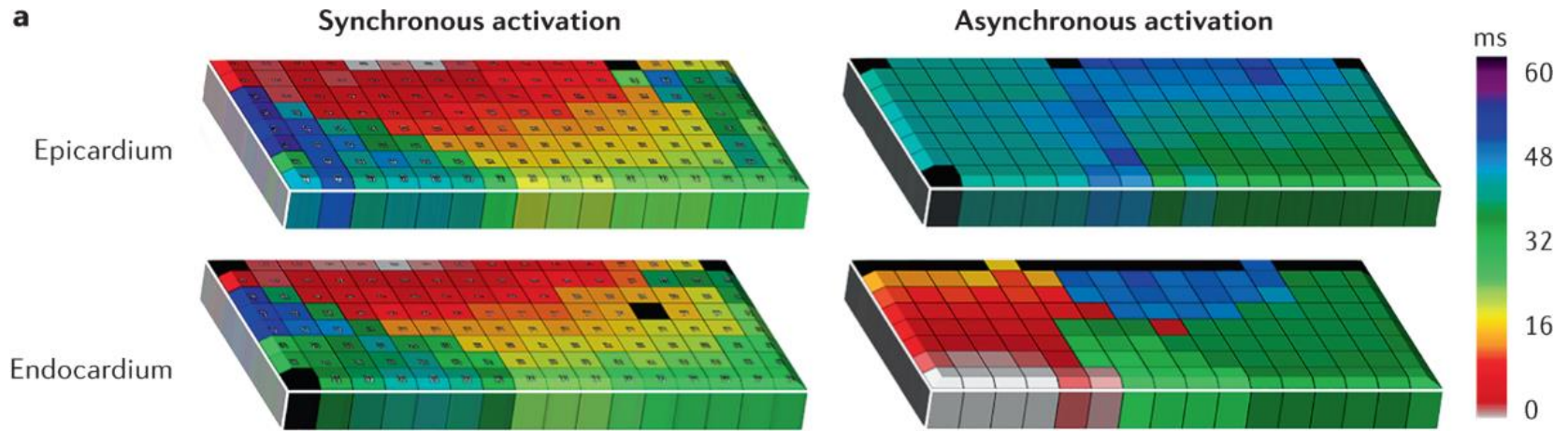


**Epicardial:
Outside the Heart**



**Endocardial:
Inside the Heart**

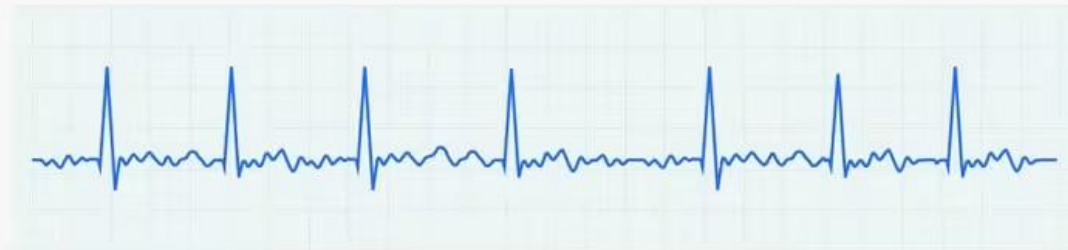




 Focal fibrillation waves



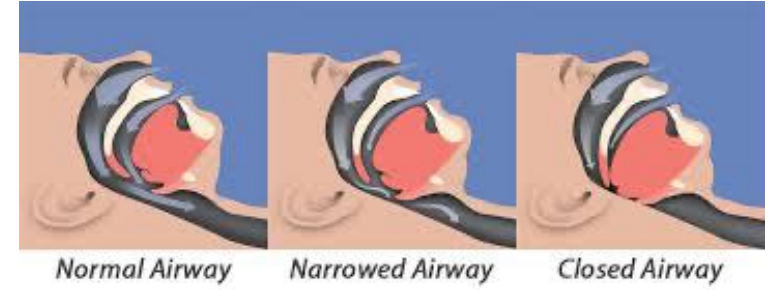
Normal ECG

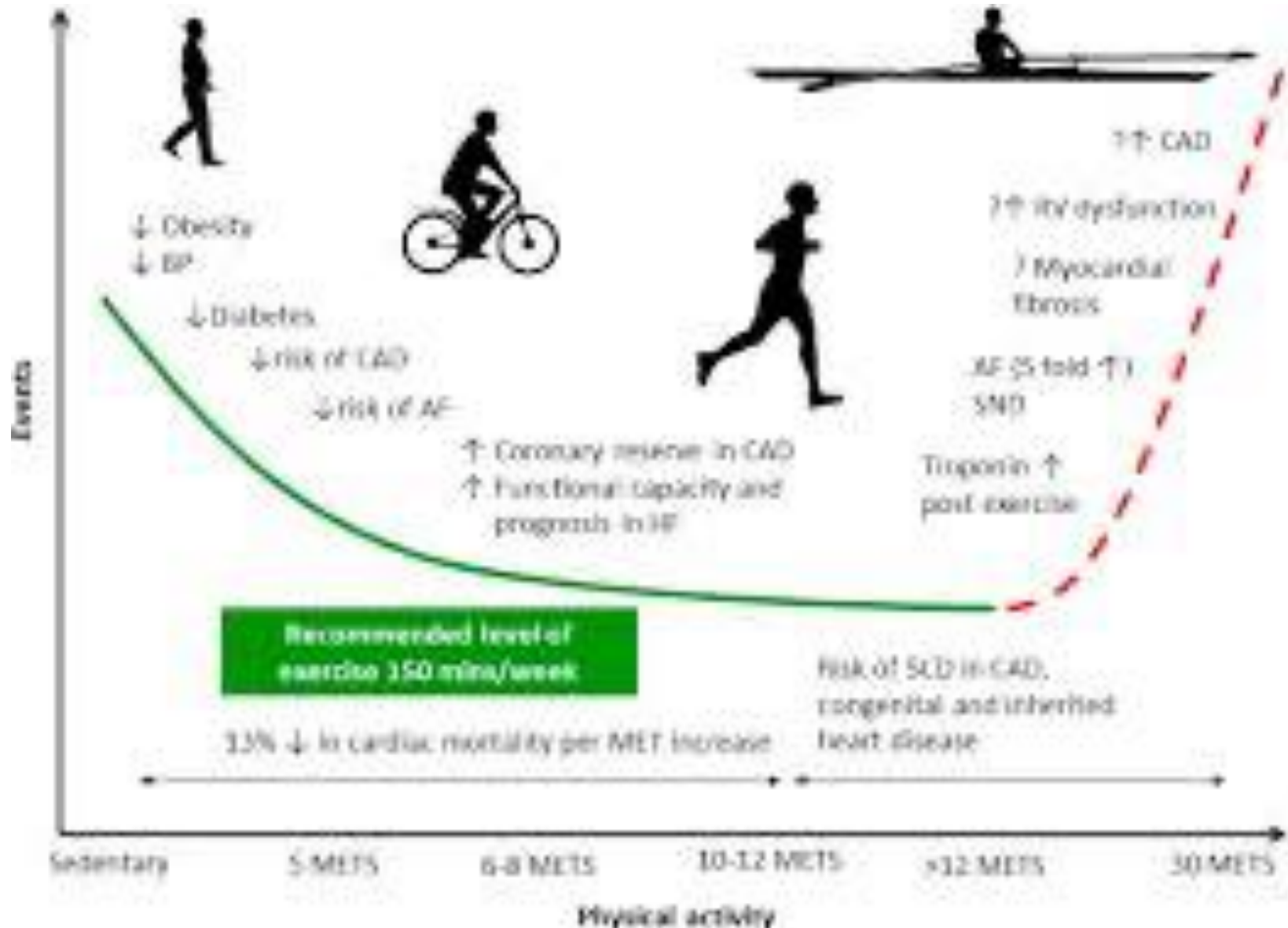


Atrial fibrillation

Causes of Atrial Fibrillation

- Alcohol use: even one drink a day increases risk of atrial fibrillation
- Tobacco use
- Hypertension
- Sleep apnea: 85% of people with atrial fibrillation have sleep apnea
- Heart failure: chambers often enlarge and predispose to atrial fibrillation
- Valvular heart disease: especially mitral stenosis, but any valve disease
- Obesity: also associated with sleep apnea and hypertension
- Intense exercise especially cycling, nordic skiing



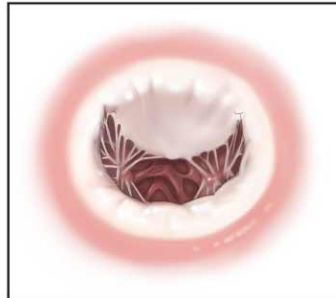


Concerns for People with Atrial Fibrillation

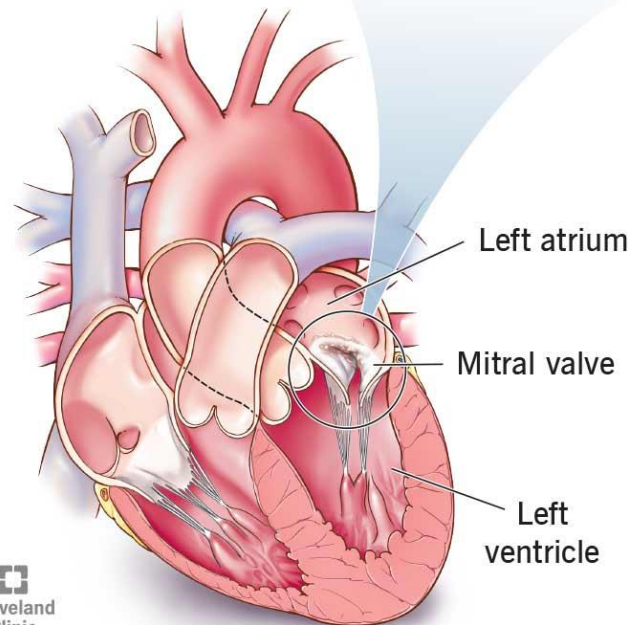
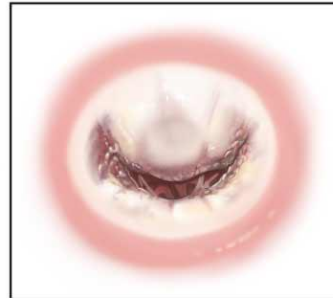
- Symptoms
 - Fatigue is most common symptom
 - Palpitations, heart racing, heart pounding, irregular beating
- Heart Failure
 - Lasting AF for over 3 weeks at 120bpm or more weakens heart
 - Shortness of breath, unable to breathe while lying flat
- Stroke Risk
 - Mitral stenosis valve disease, mechanical heart valves: need warfarin lifelong
 - CHA2DS2-VASc score: if 2 or more, need an anticoagulant lifelong

Mitral valve stenosis

Healthy mitral valve



Mitral valve stenosis



- Congestive heart failure - 1 point
- Hypertension - 1 point
- Age over 75yrs - 2 points
- Diabetes - 1 point
- Stroke or TIA - 2 points
- Vascular disease (CAD, carotid artery disease, PAD) - 1 point
- Age 65-74 - 1 point
- Sex category female - 1 point

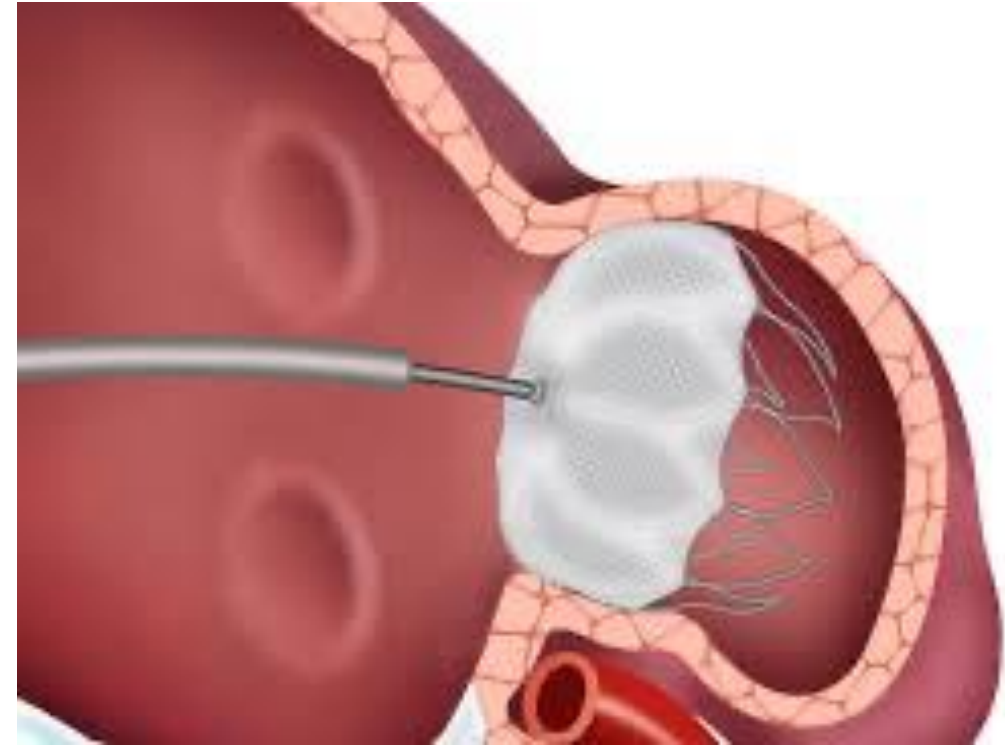
- Anticoagulate LIFELONG when score is 2 or more
- Anticoagulants:
 - Not aspirin
 - Warfarin
 - Apixaban (Eliquis): Best stroke prevention, least bleeding. Get from CANADA.
 - Rivaroxaban (Xarelto)
 - Pradaxa (Dabigatran)

Stroke Prevention if Cannot Anticoagulate

- Bleeding or bleeding risk may prevent use of anticoagulants
- Can consider blocking off the area where *MOST* (but not all) clots originate
- LEFT ATRIAL APPENDAGE



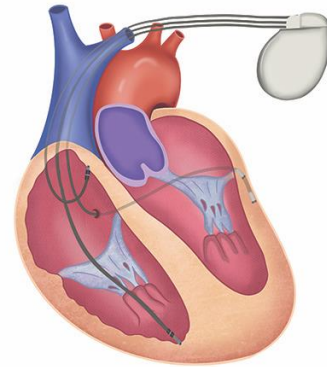
Left Atrial Appendage



- Rate control: Slows down atrial fibrillation when it's occurring
 - Does not prevent or stop atrial fibrillation
 - Metoprolol
 - Diltiazem
 - AV node ablation with pacemaker ("Ablate and Pace")
- Rhythm control: Get person out of atrial fibrillation and prevent its return
 - Flecainide, sotalol, dofetilide (Tikosyn), amiodarone: freedom from AF 30-50% over 5 years
 - Atrial fibrillation ablation: freedom from AF 50-75% over 5 years
 - Less successful as AF progresses from paroxysmal (75%) to persistent (50-60%) to long-standing persistent (30%)

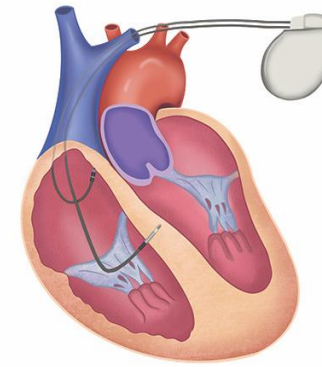
- Permanent rate control
- Bypasses atrial fibrillation and makes ventricles (pulse) regular, not fast, not slow
- Excellent for treating symptoms from atrial fibrillation
- Used when patient has failed both medications and AF ablation or too ill or elderly for safe AF ablation
- Pacemaker is placed, then AV node ablation performed
- Patient will be dependent on pacemaker

Cardiac resynchronization therapy



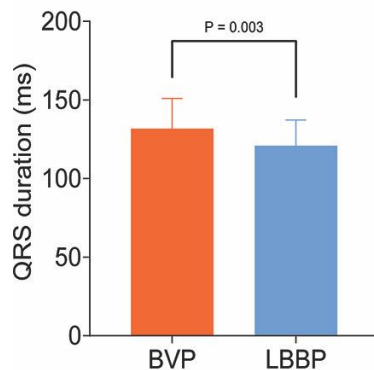
BVP

Versus

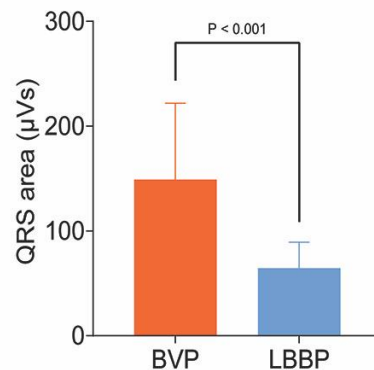


LBBP

Electrical synchrony

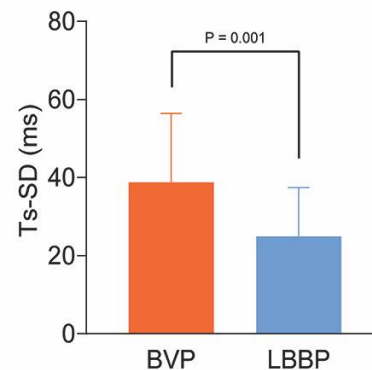


QRS duration

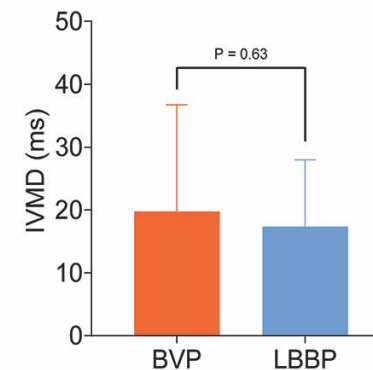


QRS area

Mechanical synchrony

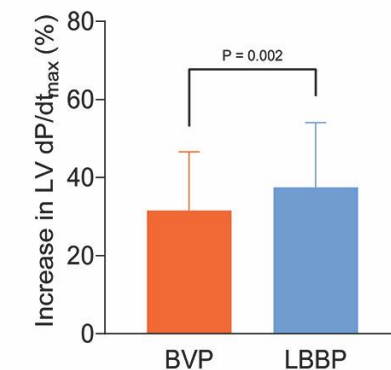


Ts-SD



IVMD

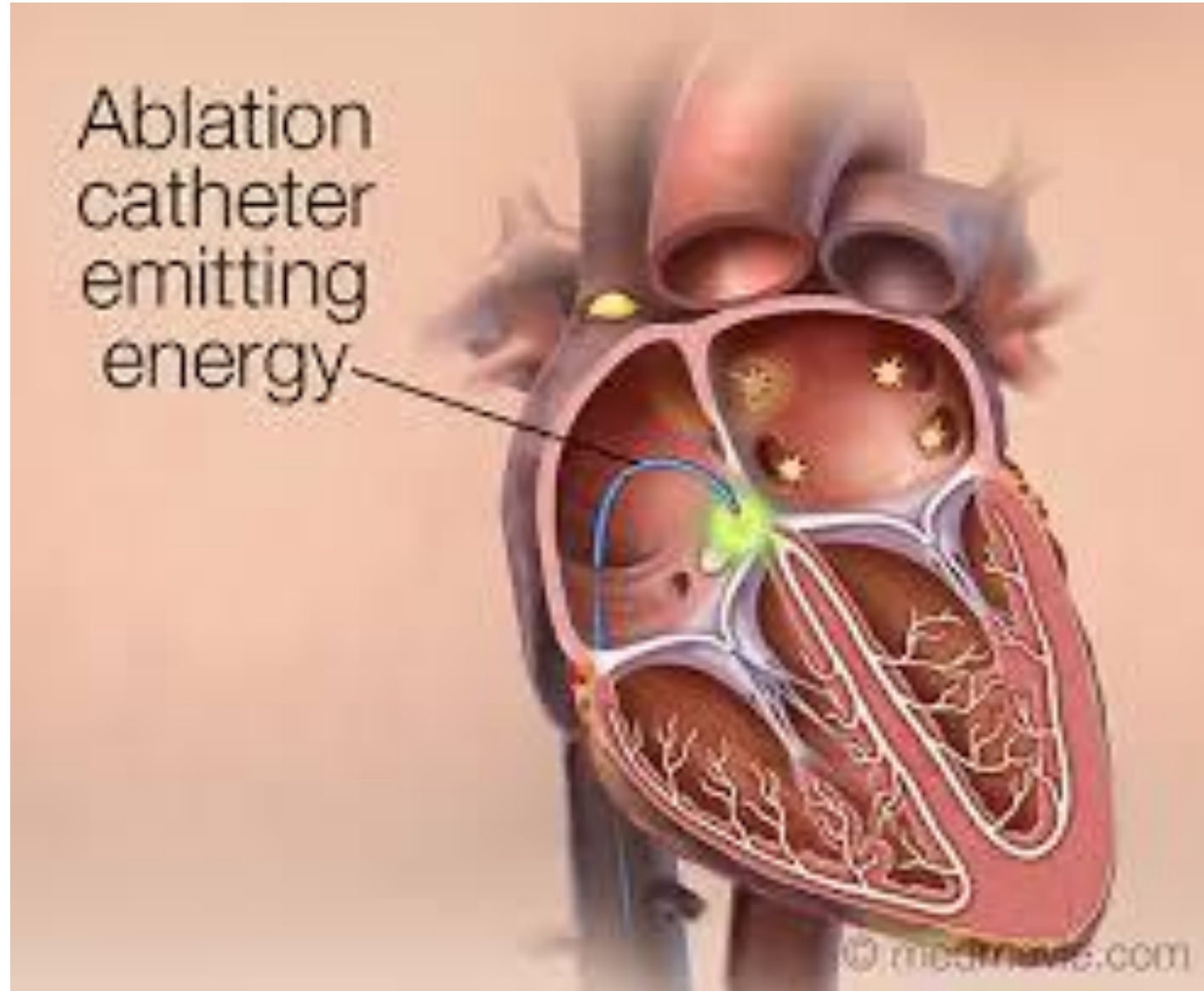
Hemodynamics



Increase in dP/dt_{max}

Atrial Fibrillation: Catheter Ablation

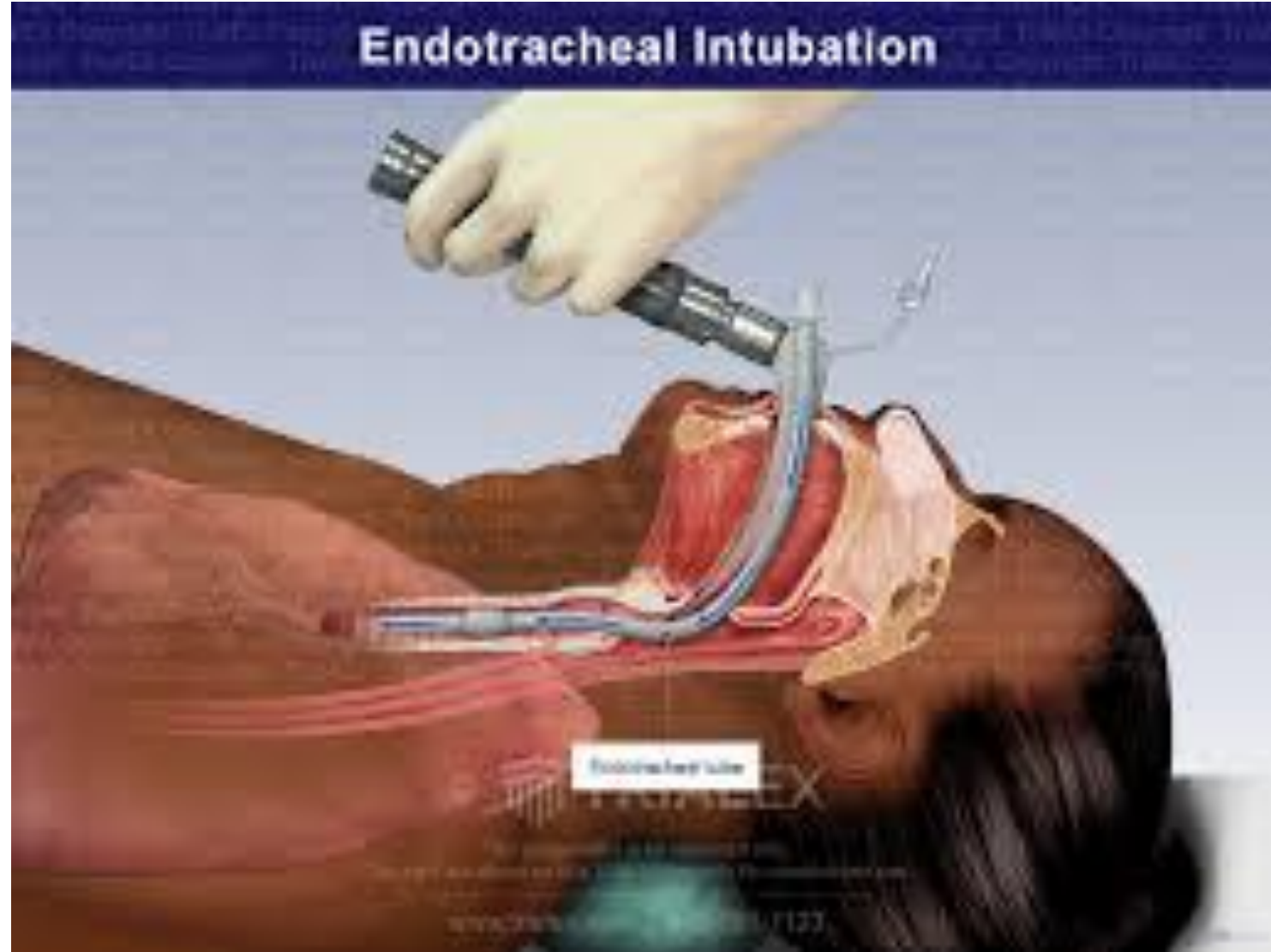
Oussama Lawand, MD
Clinical Cardiac Electrophysiology,
Boulder Heart

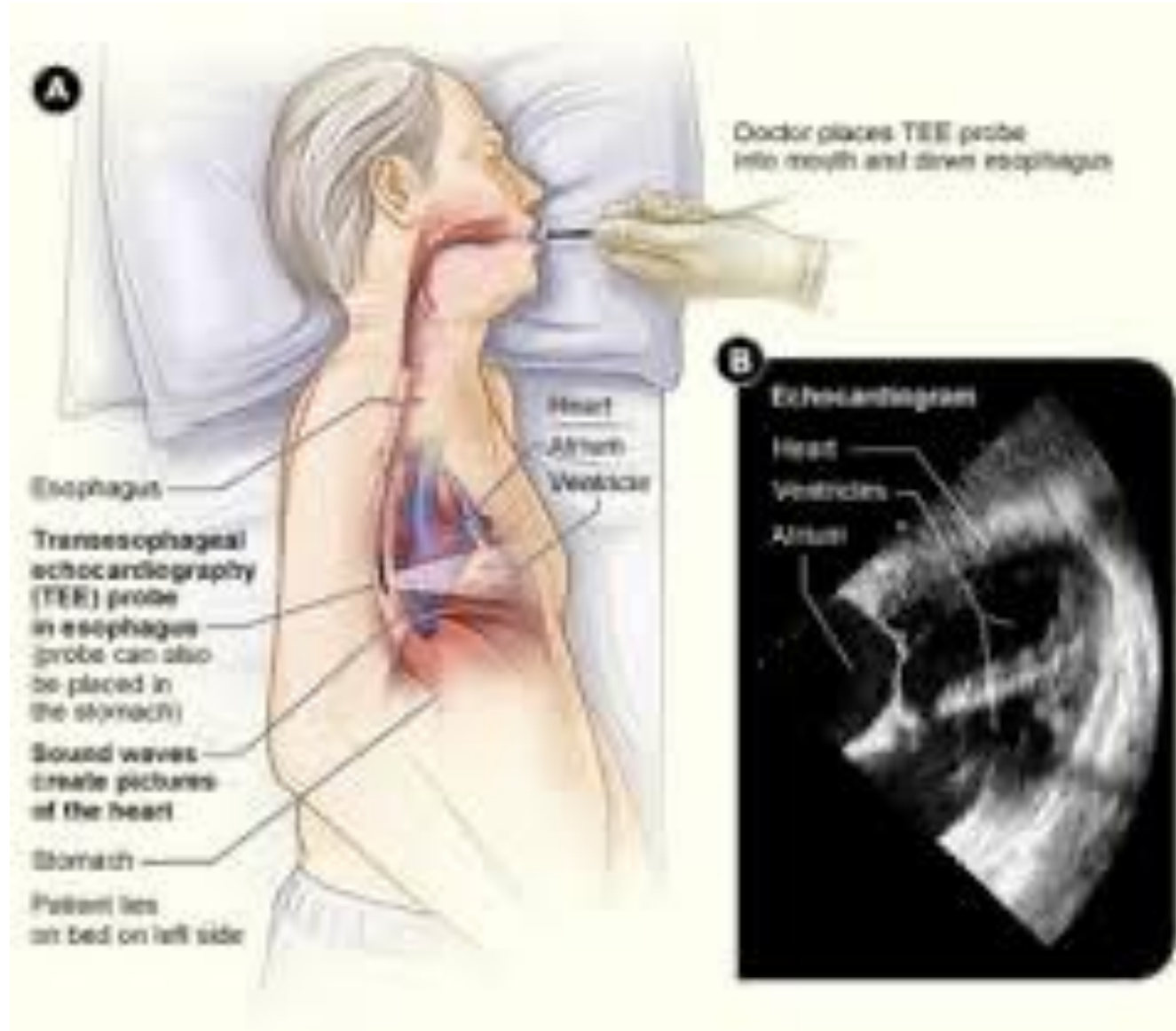


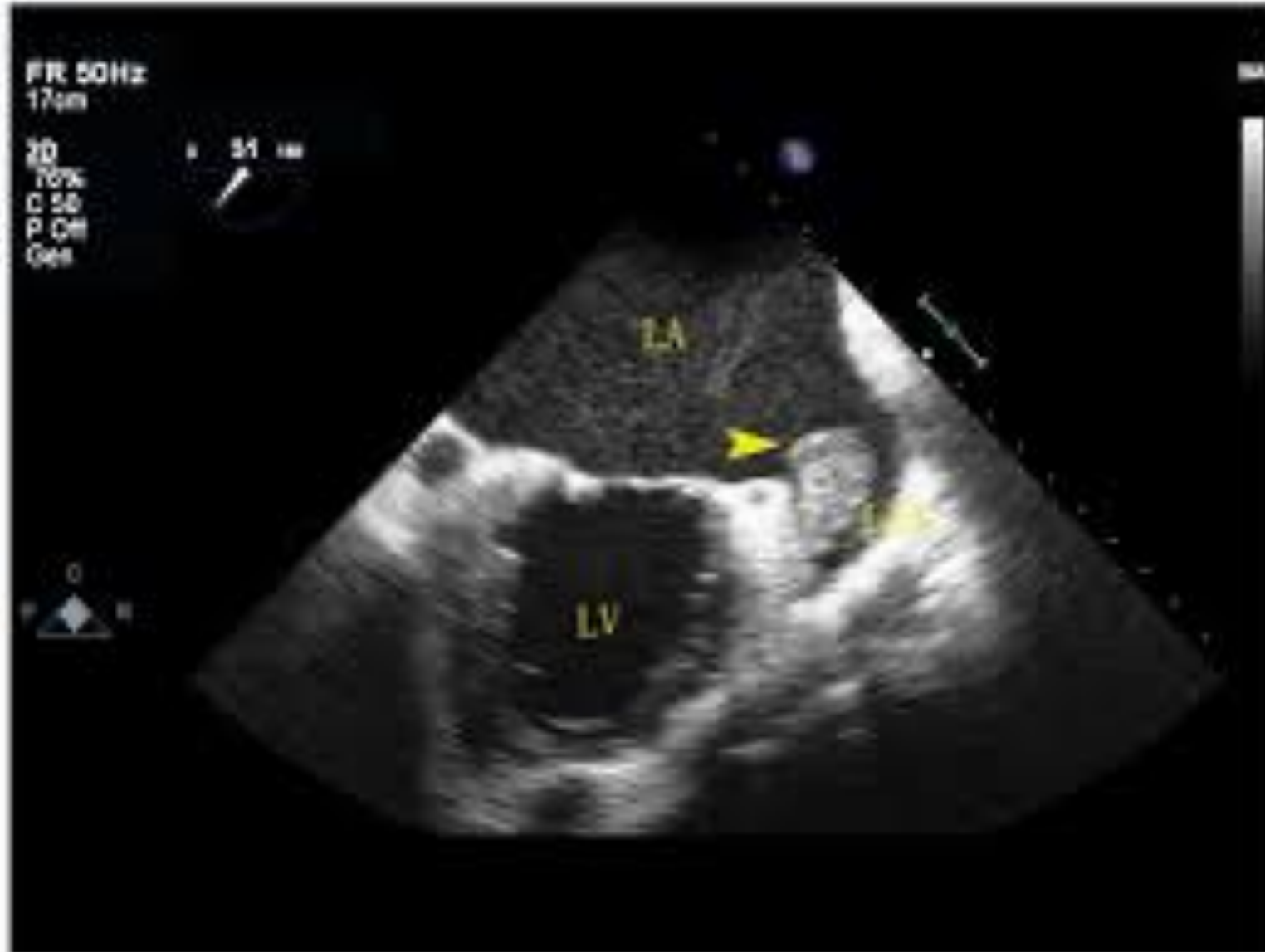
- Set up
- Method
- Risks
- Safety measures
- Follow up
- Post Ablation atrial fibrillation treatment
- Repeat ablation

- Anesthesia and EP see patient and family and obtain consent
- Bring patient to the room
- Attach ECGs, monitors, and CARTO mapping patches
- Set up magnet
- Set up table for access and catheters
- CARTO representative sets up mapping software

- General anesthesia with endotracheal tube
- Transesophageal echocardiogram to assure no clot in left atrial appendage





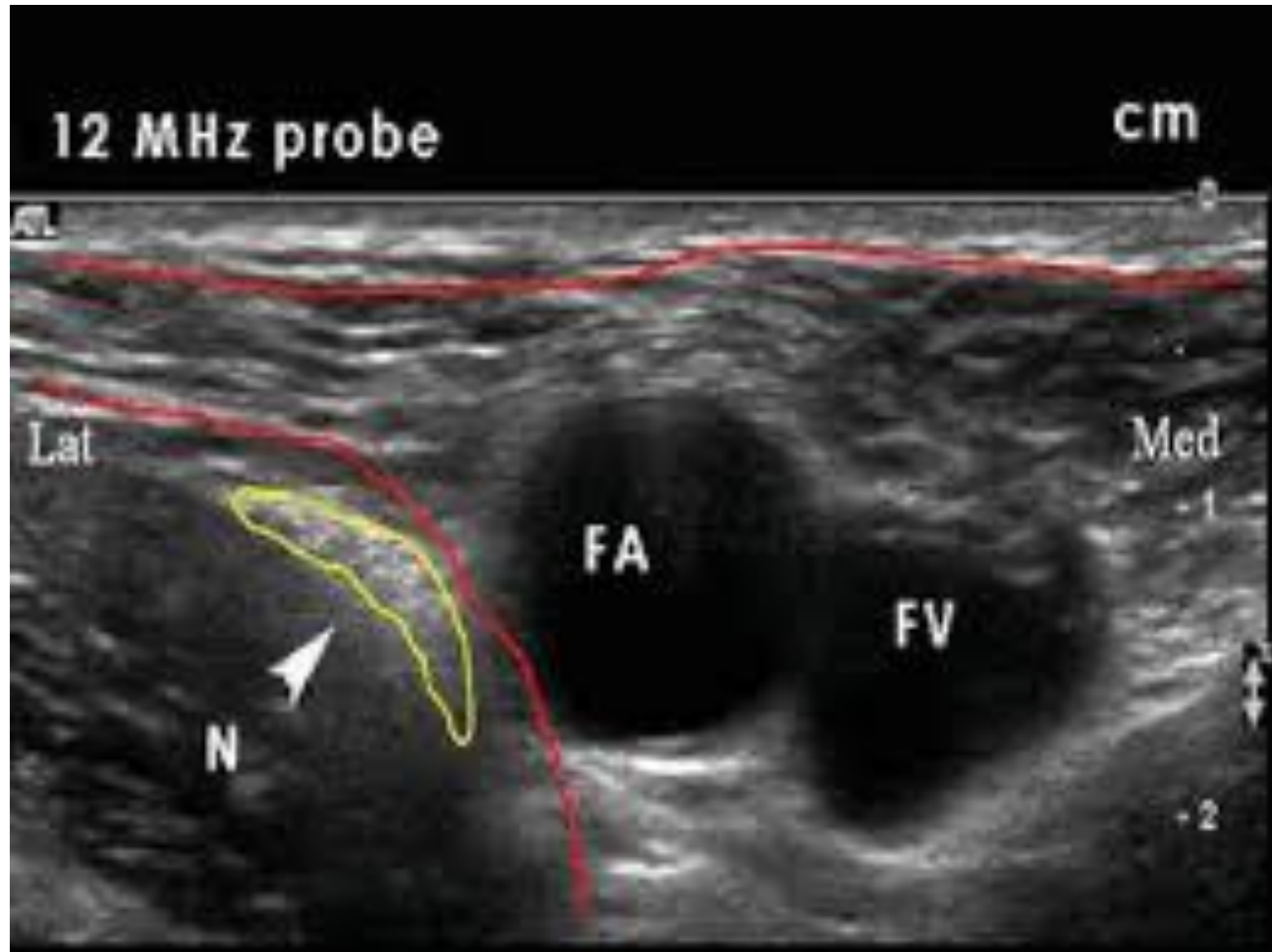


Access Femoral Vein

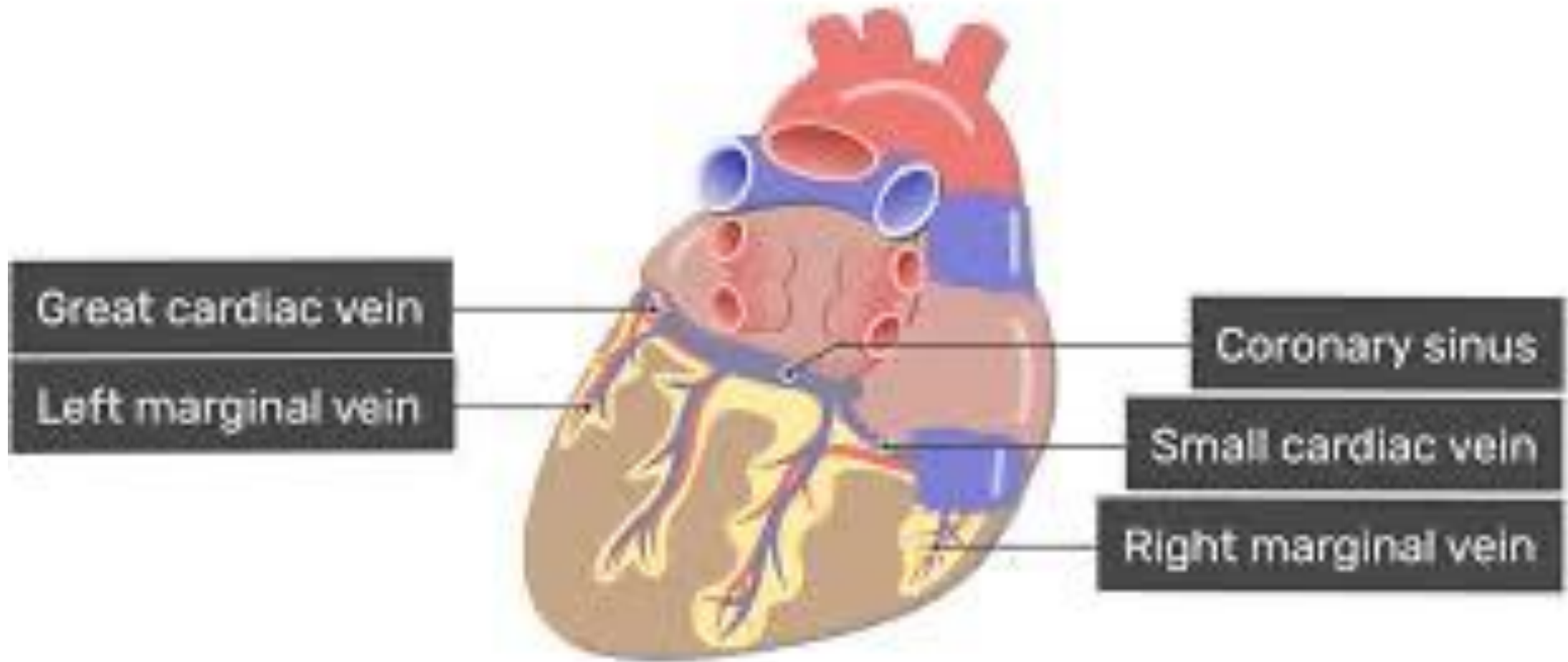
- Ultrasound-guided
- Three catheters in the right femoral vein





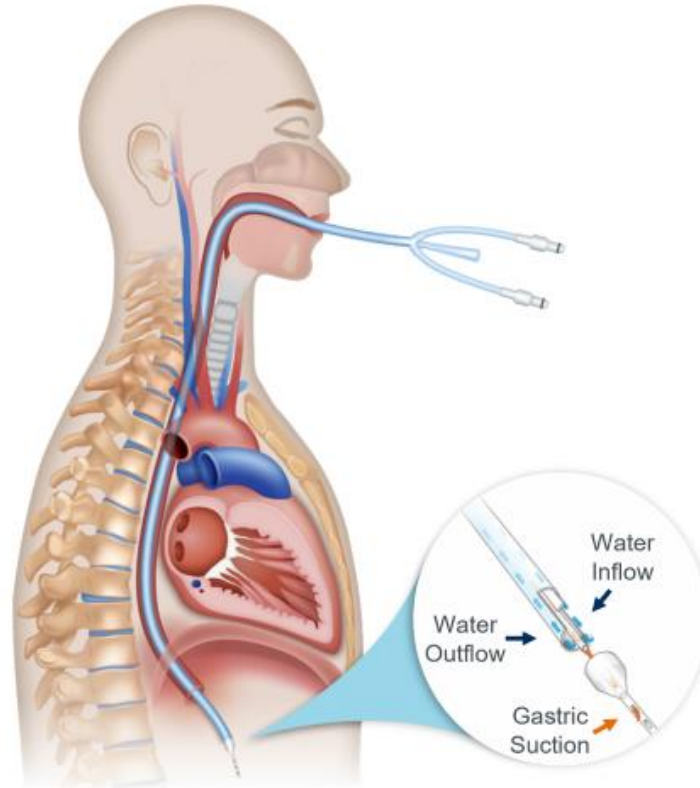


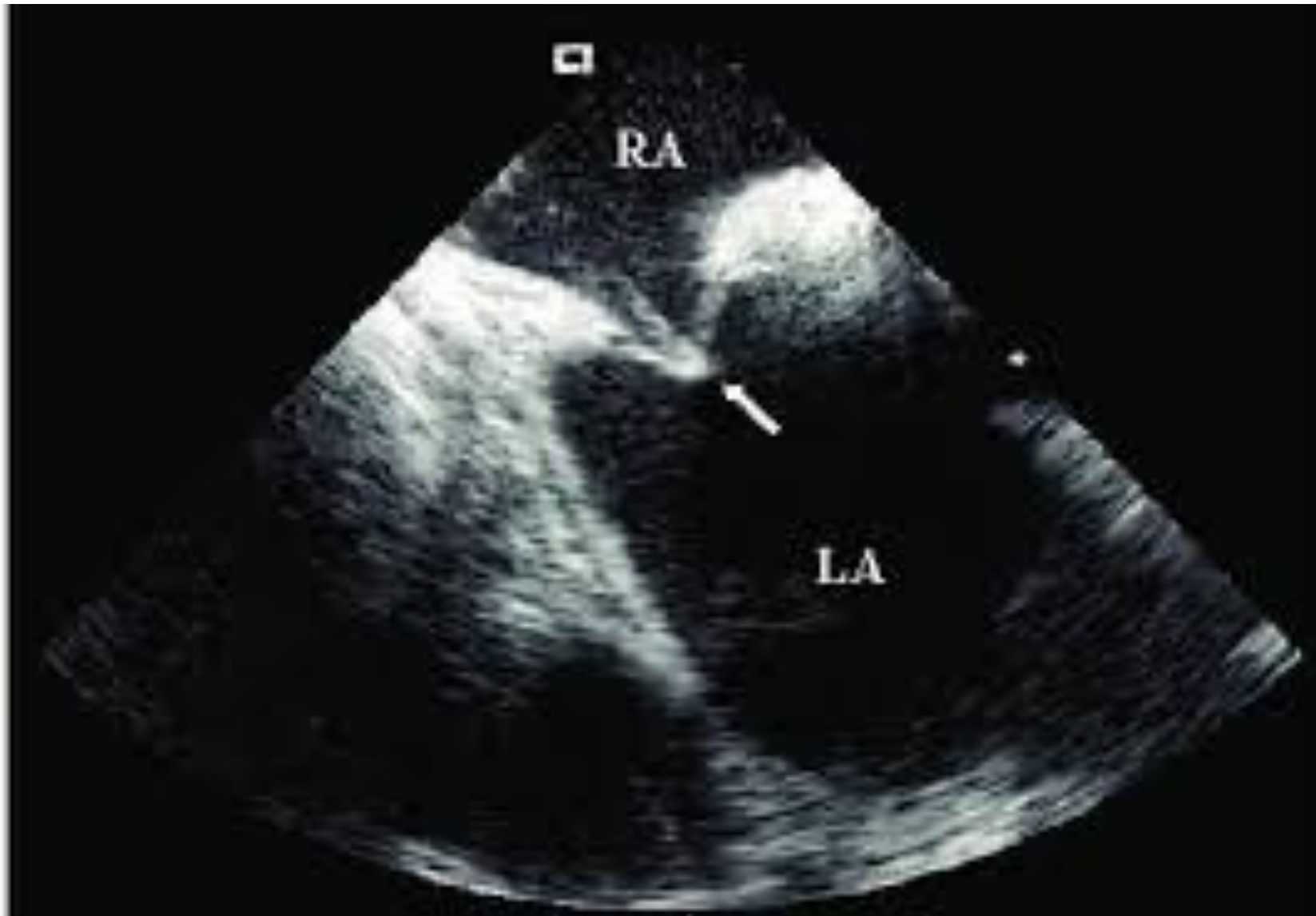
- 8Fr sheath for mapping
 - Changed to longer deflectable sheath for mapping and ablation
- 7Fr sheath for coronary sinus catheter
 - Vein that runs just below the left atrium and records electrical signals
- 9Fr for intracardiac echo





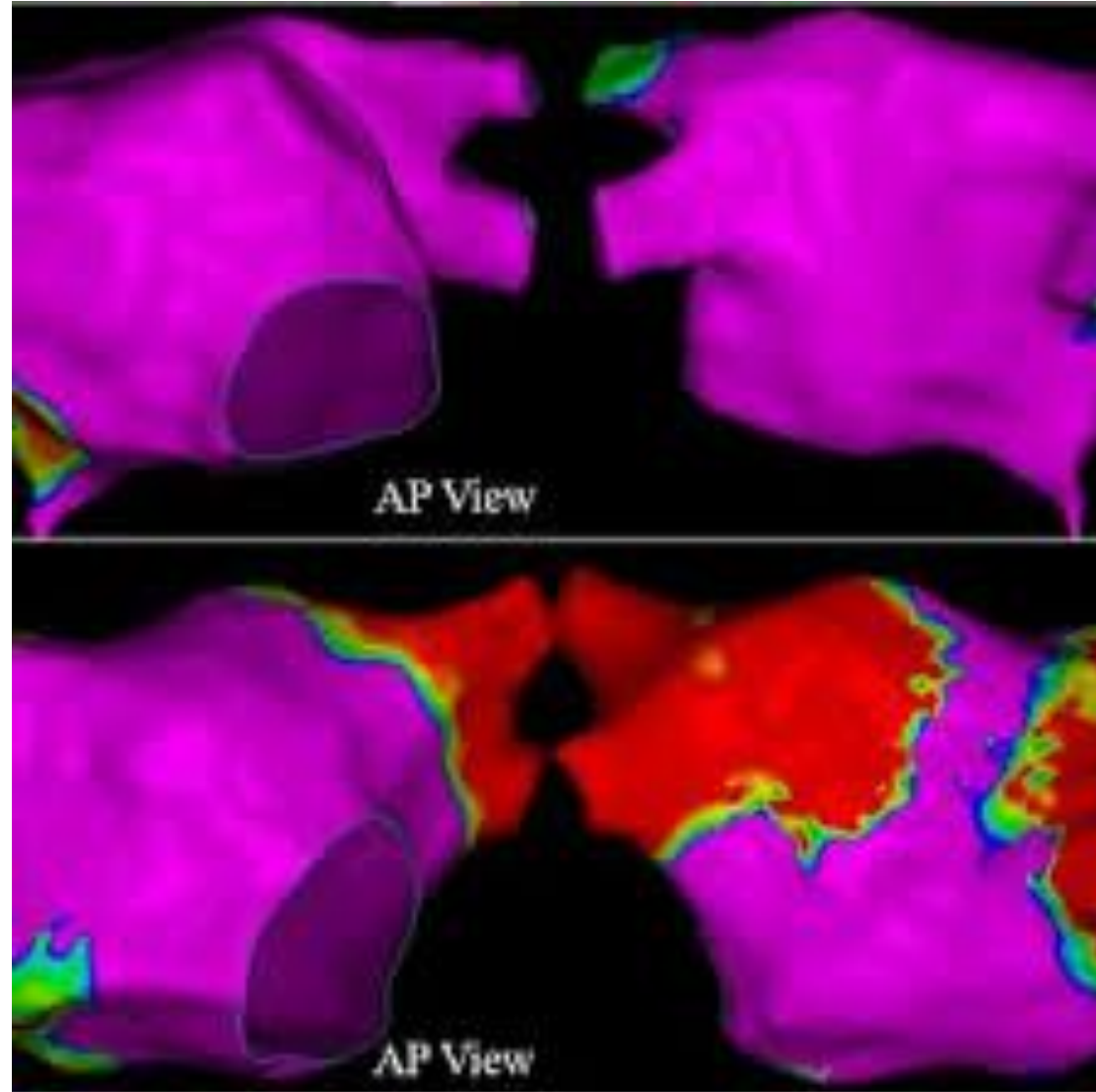
- Anesthesia places esophageal cooling probe
- Esophagus is adjacent to the back wall of the left atrium
- Heating esophagus is bad
 - Atrioesophageal fistula: rare but fatal



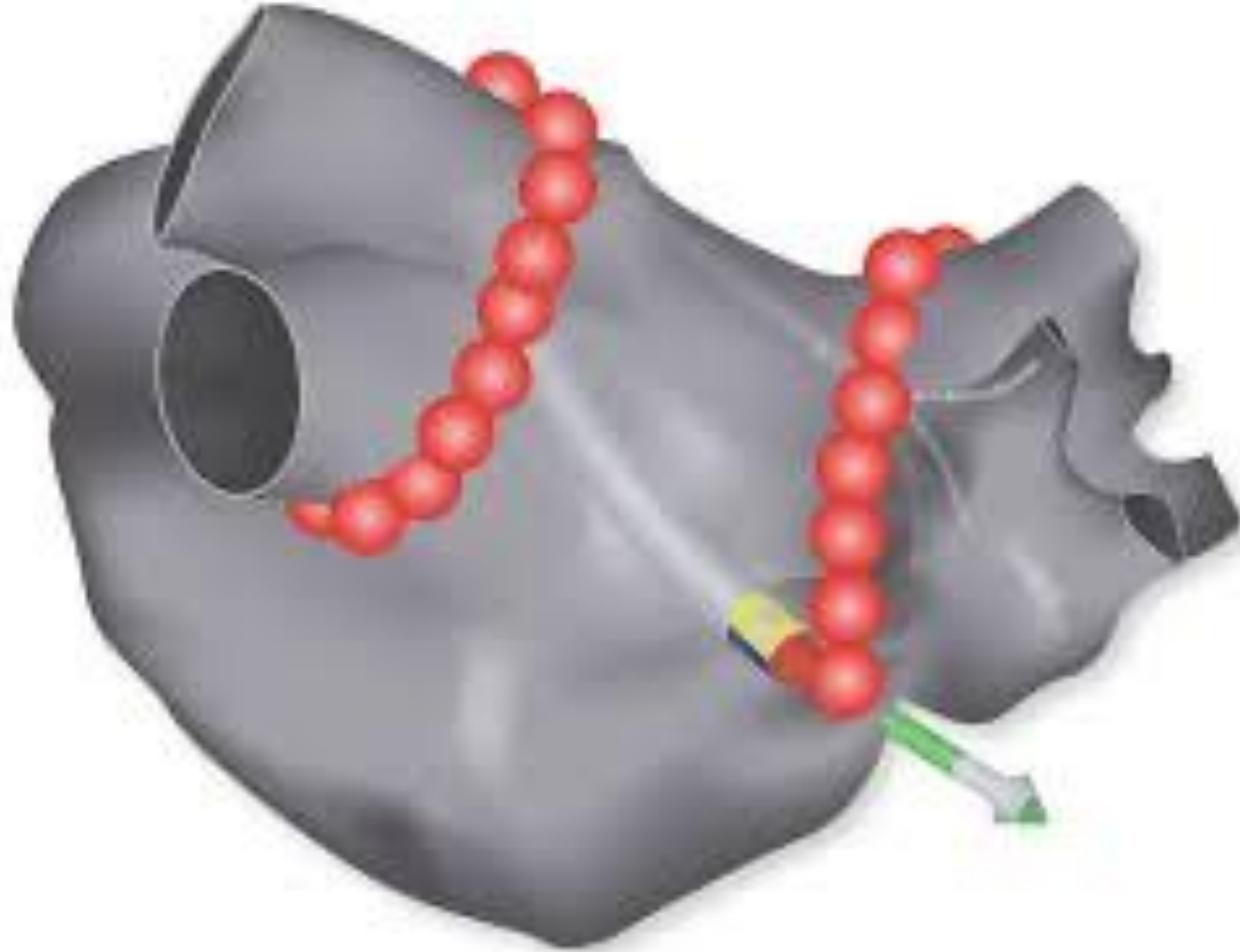


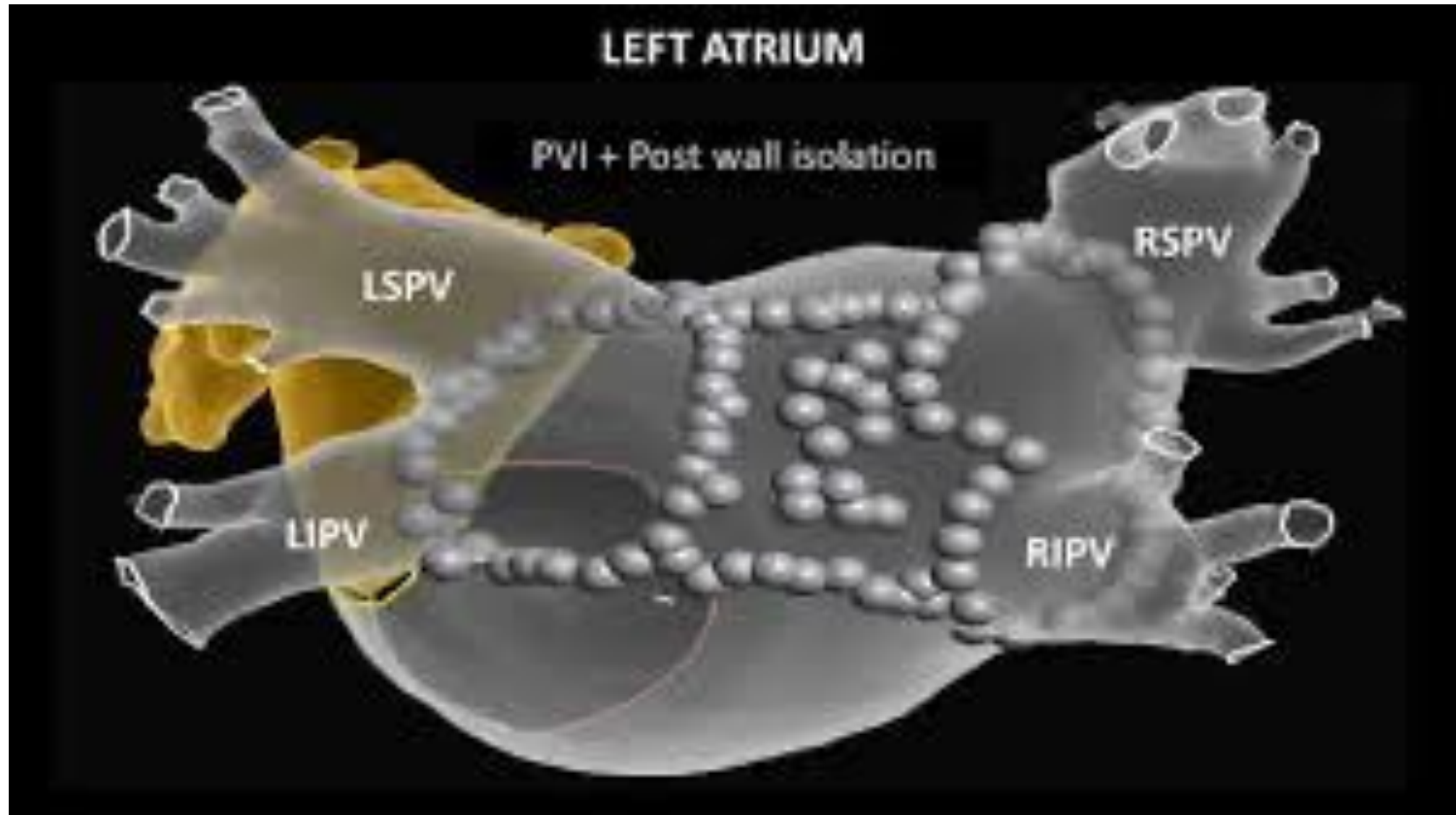


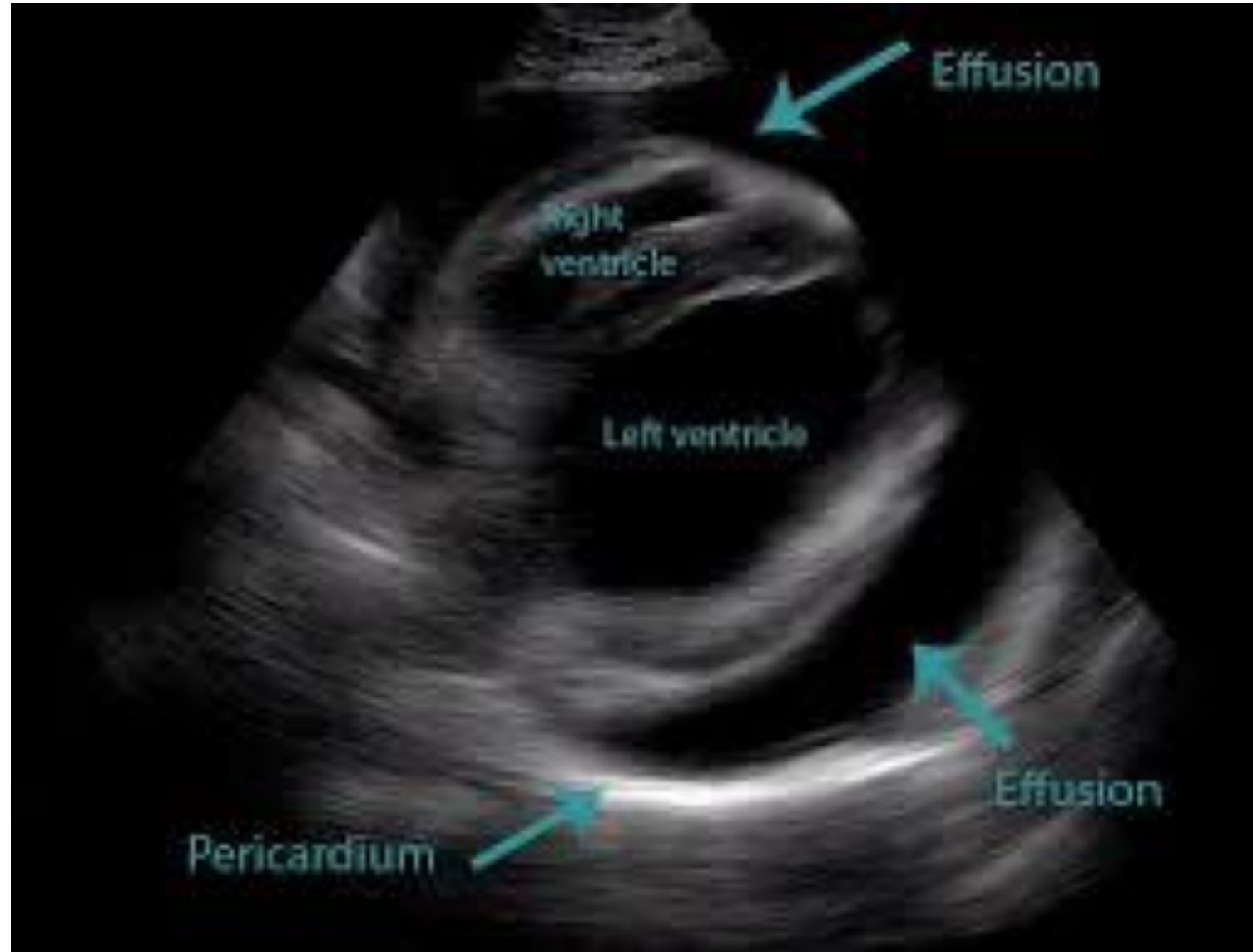


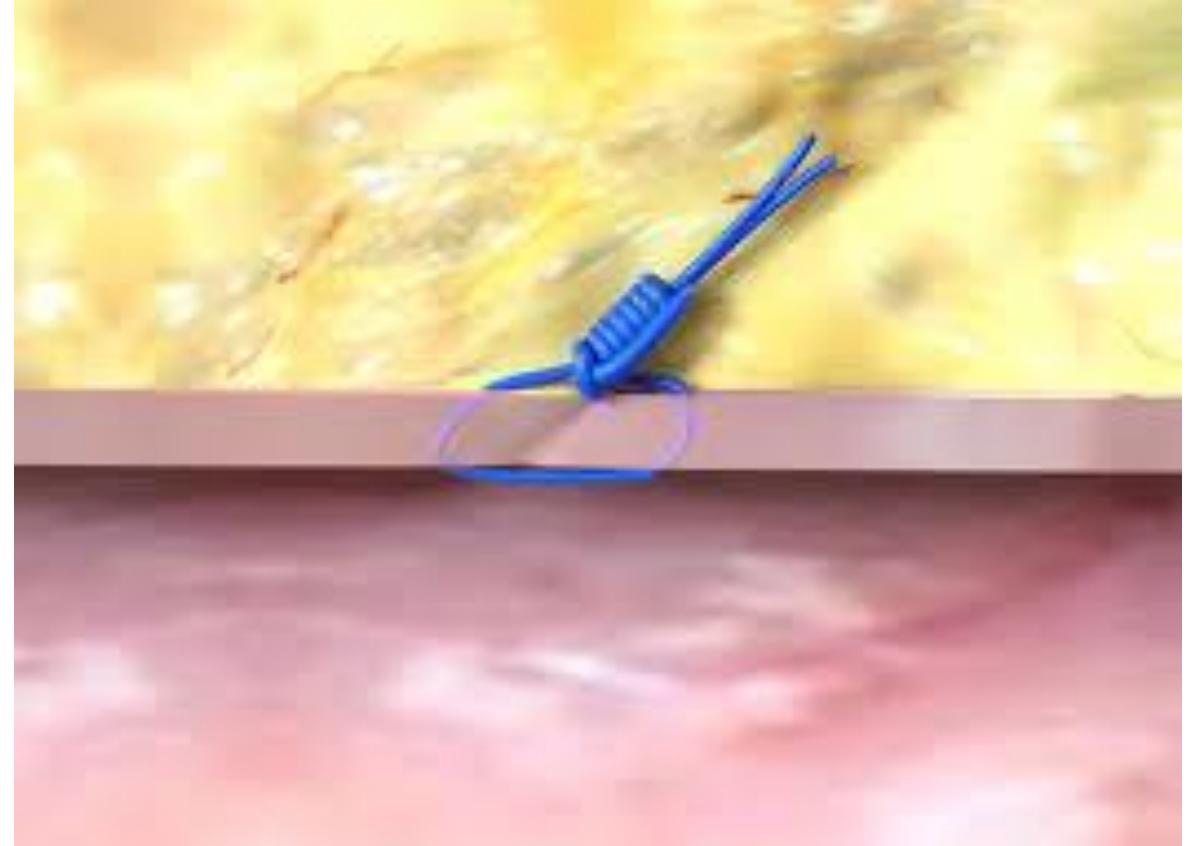
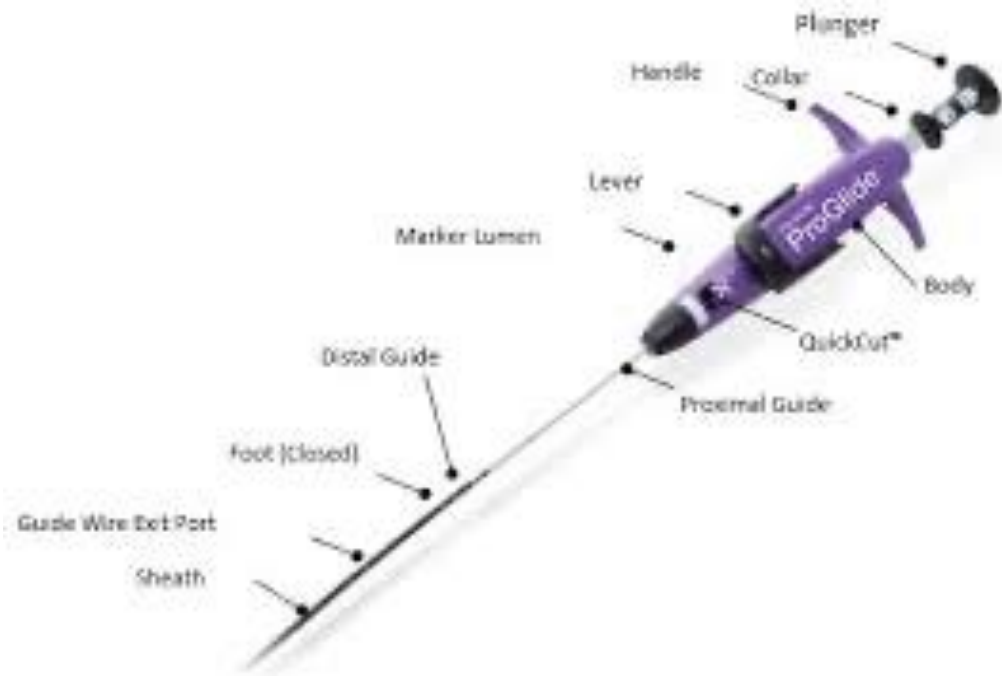












Post Atrial Fibrillation Ablation

- Takes 2.5-4 hours, depending on how advanced the atrial fibrillation is
- Patients recover for about two hours
- Same-day procedure

- Visit in one month and three months
- Not uncommon to have some atrial fibrillation for up to three months
- If have AF lasting more than 12 hours, report
- Need cardioversion
- If ongoing atrial fibrillation three months post ablation, repeat ablation

- Atrial fibrillation is a complex, progressive rhythm
- Avoiding causes and triggers helps, especially early in AF
- Most people with AF need anticoagulation before, during, and after ablation
- Prevent progression of atrial fibrillation with early rhythm control
- Atrial fibrillation ablation is the best we have for rhythm control
 - But nothing cures atrial fibrillation
- If all else fails, consider permanent rate control with ablate and pace

Atrial Fibrillation: Stroke and Blood Thinning Medications...What else is available?

Srinivas Iyengar, MD
Interventional Cardiologist
Structural Heart Director, Boulder Heart

- Irregular heart rhythm
- Basically, the top parts of the heart (“atria”) don’t communicate electrically with the bottom (“ventricles”)
- Results in symptoms of SOB, light-headedness, and palpitations

- High blood pressure
- Heart attacks
- CAD
- Abnormal heart valves
- Heart defects you're born with (congenital)
- An overactive thyroid gland or other metabolic imbalance
- Exposure to caffeine, tobacco or alcohol

- ECG is mandatory
- Not every “irregular heart rhythm” is AFib!
- PVCs, APCs, skipped beats can all mimic feelings of AFib
- AFib does not have to be chronic, it can be short-lasting or come/go (i.e., PAF)

- Medications to control HR (i.e., beta-blockers, Ca-channel blockers) are first line.
- Anti-arrhythmic medications can be used to control rhythm.
- Cardioversion (either electrically or chemically) can be utilized for symptomatic AFib.
- Ablation (surgically or percutaneously) can also be utilized.

But What Else Does AFib Cause?

- Stroke!!
- The left atrial appendage (LAA), which is in the left atrium, can collect blood and form clots that can break free in patients with AFib.
- That's why we place patients with AFib who have elevated risks for stroke on blood thinners.

- Work very well as long as compliance is maintained and no side effects seen.
- Warfarin - cheap but compliance with diet/testing an issue as well maintaining adequate levels.
- NOACs - Costly, lack readily available reversal agents.
- All the above can exacerbate bleeding.

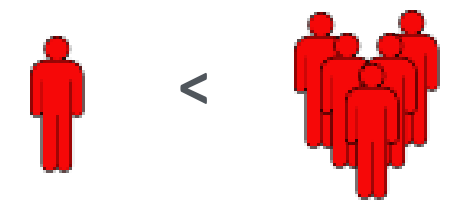
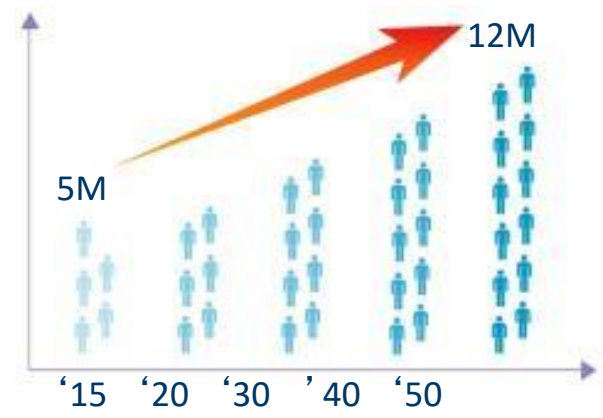


AFib is a Growing Problem Associated with Greater Morbidity and Mortality

- Higher stroke risk for older patients and those with prior stroke or TIA
- 15-20% of all strokes are AFib-related
- AFib results in greater disability compared to non-AFib-related stroke

AF = most common cardiac arrhythmia, and growing

AF increases risk of stroke



~5 M
people with AF in U.S., expected to more than double by 2050¹

5x
greater risk of stroke with AF²

1. Go AS, et al, Heart Disease and Stroke Statistics—2013 Update: A Report From the American Heart Association. Circulation. 2013; 127: e6-e245.
 2. Holmes DR, *Seminars in Neurology* 2010;30:528–536.
 Wolf PA et al, Duration of Atrial Fibrillation and the Imminence of Stroke: The Framingham Study, *Stroke* 1983; 14:664-667



AFib-related Strokes are Debilitating

Stroke

#1 cause of **adult disability** worldwide¹

AF-related Stroke

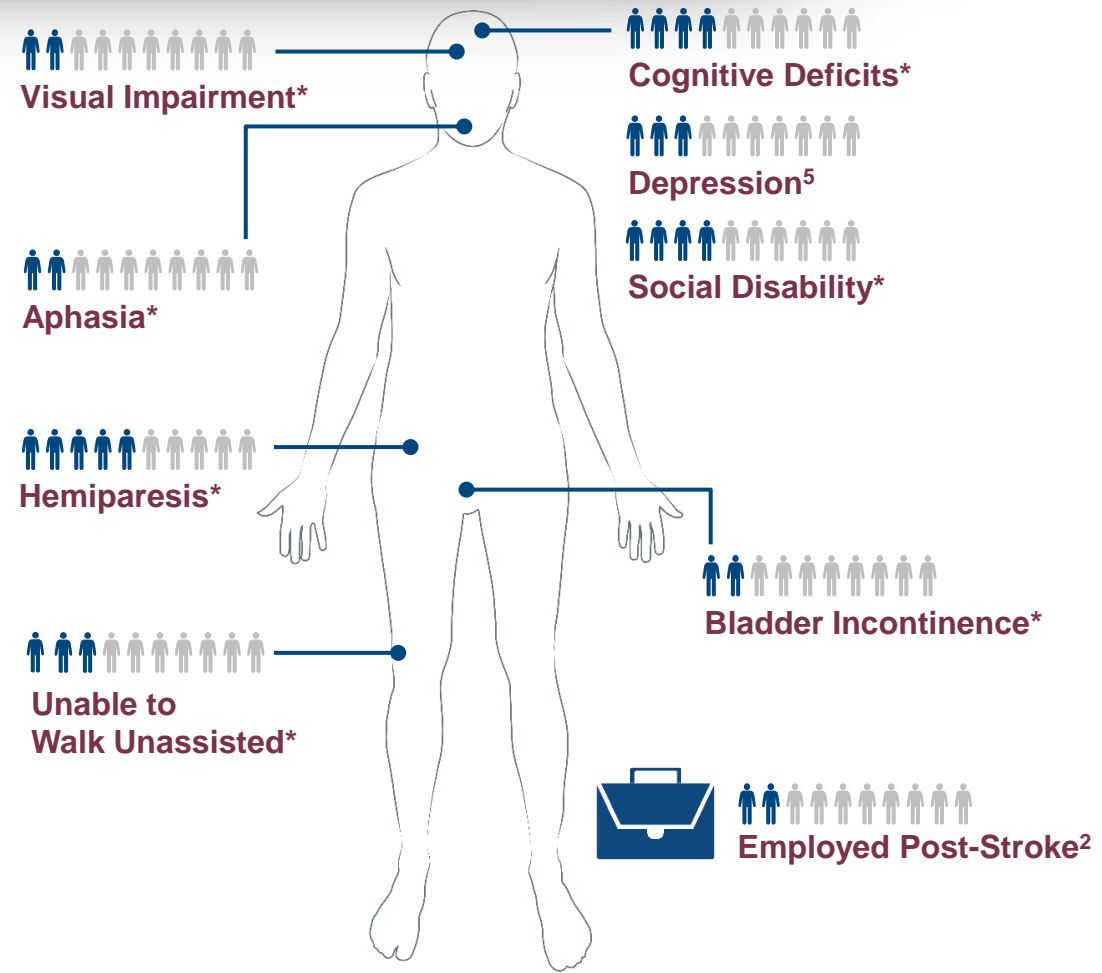
1.5X higher **disability**^{3**}

2X higher **mortality**^{3**}

70% result in **death or permanent disability**⁶

*at 6 months post-stroke⁴

**compared with stroke patients without AF

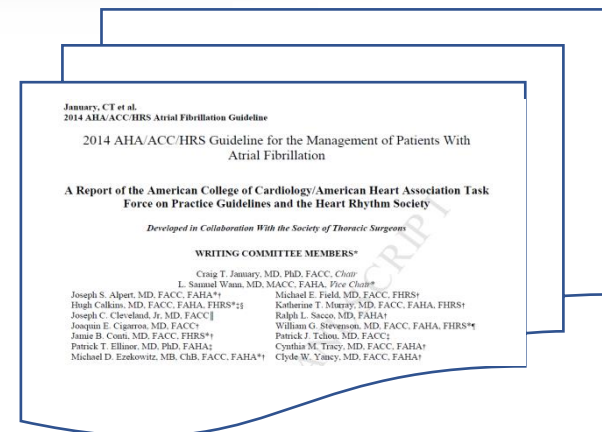


¹Chee and Tan. *Med J Malaysia* 69.3 (2014): 119-23. ²Sreedharan et al. *Journ of the neurological sciences* 332.1 (2013): 97-101. ³Lamassa et al. *Stroke* 32.2 (2001): 392-398. ⁴Kelly-Hayes et al. *Journ of Stroke and Cerebrovascular Diseases* 12.3 (2003): 119-126. ⁵Loo and Gan. *International Journ of Stroke* 7.2 (2012): 165-167. ⁶Holmes DR, *Seminars in Neurology* 2010;30:528-536.



2014 ACC/AHA/HRS Treatment Guidelines to Prevent Thromboembolism in Patients with AF

- Assess stroke risk with CHA₂DS₂-VASc score
 - Score 1: Annual stroke risk 1%, oral anticoagulants or aspirin may be considered
 - Score ≥2: Annual stroke risk 2%-15%, **oral anticoagulants are recommended**
- **Balance stroke risk reduction benefit vs. bleeding risk**



2014 AHA/ACC/HRS Guideline for the Management of Patients with AF

CHA ₂ DS ₂ VASc Score	Recommendation
0	No anticoagulant
1	Aspirin (81-325 mg daily) or warfarin (INR 2-3)
≥2	Oral anticoagulants are recommended (warfarin (INR 2-3), dabigatran, rivaroxaban or apixaban)

Anticoagulant Therapy Carries Risk of Intracerebral Hemorrhage or Death



WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE



**Spontaneous intra-
parenchymal bleed**



**Hemorrhagic
transformation**



Validated Scoring Systems to Assess Stroke Risks

CHA₂DS₂VASc Score (Stroke Risk)³

	Condition	Points
C	Congestive heart failure	1
H	Hypertension (SBP>160)	1
A ₂	Age ≥ 75 years	2
D	Diabetes mellitus	1
S ₂	Prior stroke, TIA or thromboembolism	2
V	Vascular disease (PAD, MI)	1
A	Age 65-74 years	1
Sc	Sex category (Female)	1
TOTAL POINTS		

Score	Yearly Stroke Risk (%)		
	No Warfarin	With Aspirin ²	With Warfarin ²
0	0	0	0
1	1.3	1.0	0.5
2	2.2	1.8	0.8
3	3.2	2.6	1.1
4	4.0	3.2	1.4
5	6.7	5.4	2.3
6	9.8	7.8	3.4

3. Chest. 2010 Feb;137(2):263-72.

Validated Scoring Systems to Assess Bleeding Risks



WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

HAS-BLED Score (Bleeding risk with warfarin)⁴

	Condition	Points
H	Hypertension	1
A	Abnormal renal/liver function (1 pt each)	1 or 2
S	Hemorrhagic Stroke	1
B	Bleeding history or disposition ⁴	1
L	Labile INRs	1
E	Elderly	1
D	Current drugs (medication) or alcohol use (1pt each)	1 or 2
TOTAL POINTS		

Score	Yearly Major Bleeding Risk %
0	1.13
1	1.02
2	1.88
3	3.74
4	8.70
5+	Not well validated

Bleeding Risk Increases Over Patients' Lifetime



WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

HAS-BLED Score	Annual % Bleed Risk*	10-Year Bleeding Risk (%)**
0	0.9	8.6
1	3.4	29.2
2	4.1	34.2
3	5.8	45.0
4	8.9	60.6
5	9.1	61.5

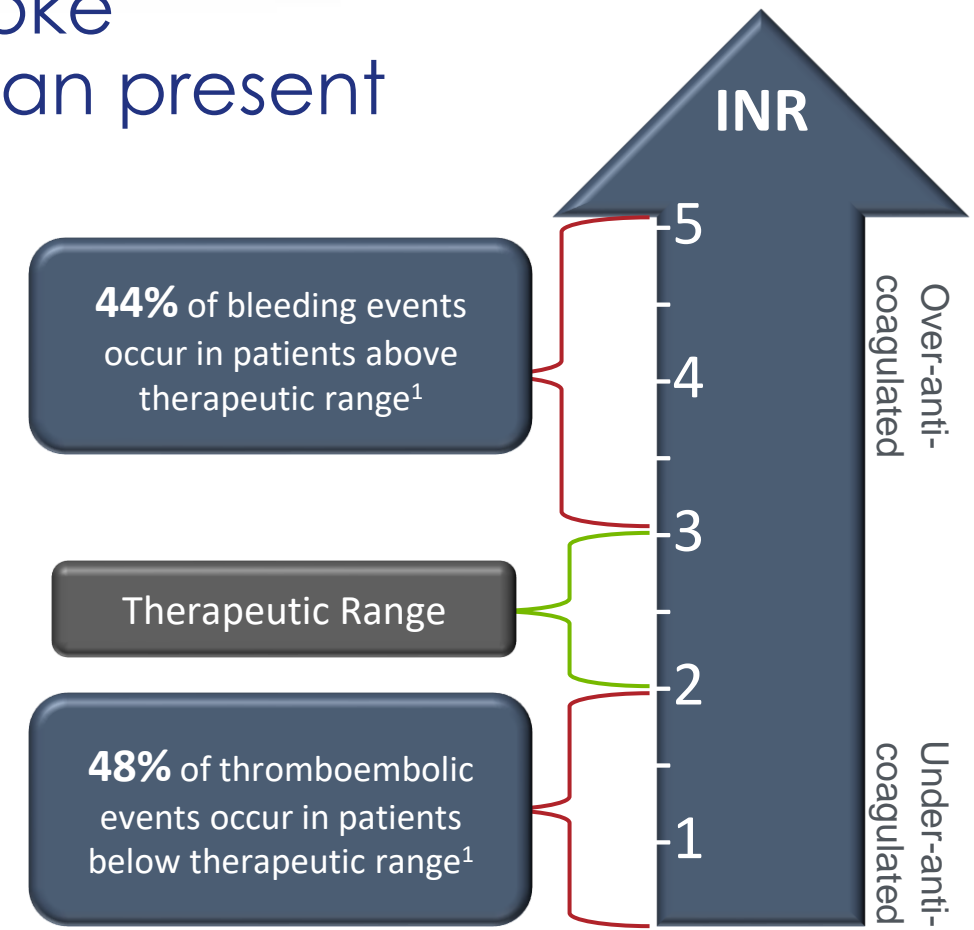
** Assumes constant risk despite increasing age and bleeding risk is independent from bleeding risk in previous years.



Stroke Treatment Option: Warfarin

Warfarin is an effective means of stroke reduction in patients with AFib but can present challenges.

- Many patients spend a significant amount of time outside of the therapeutic range.
- Warfarin tops the list for emergency hospitalizations for adverse drug events in older Americans²



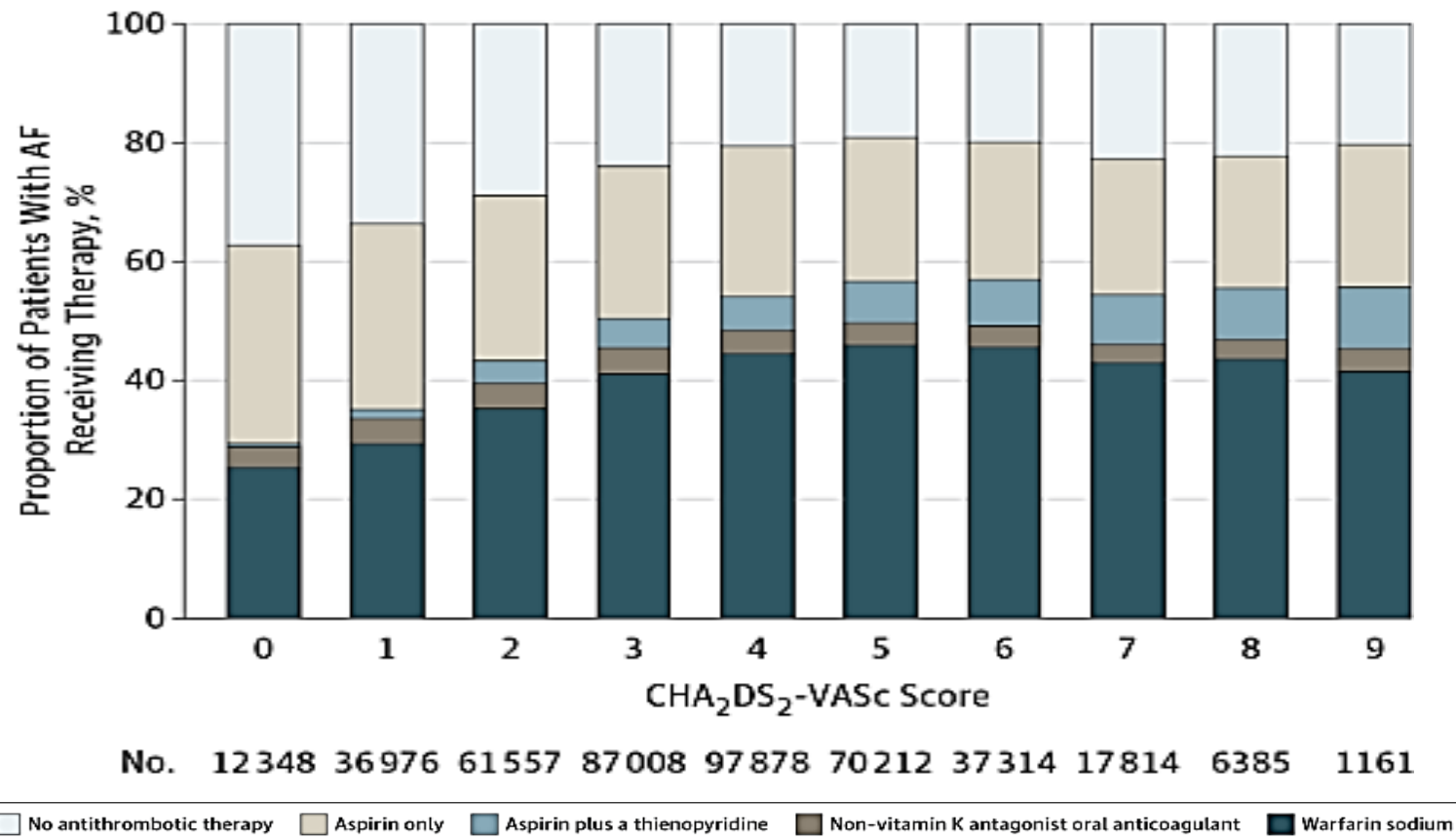
¹ Oake N, et al. *Can Med Assoc J.* 2007;176(11);1589–1594
² Budnitz, MD, MPH. et al. *Annals of Internal Medicine.* 2007;147(11); 229

Oral Anticoagulation is Standard of Care, but Compliance a Challenge



WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

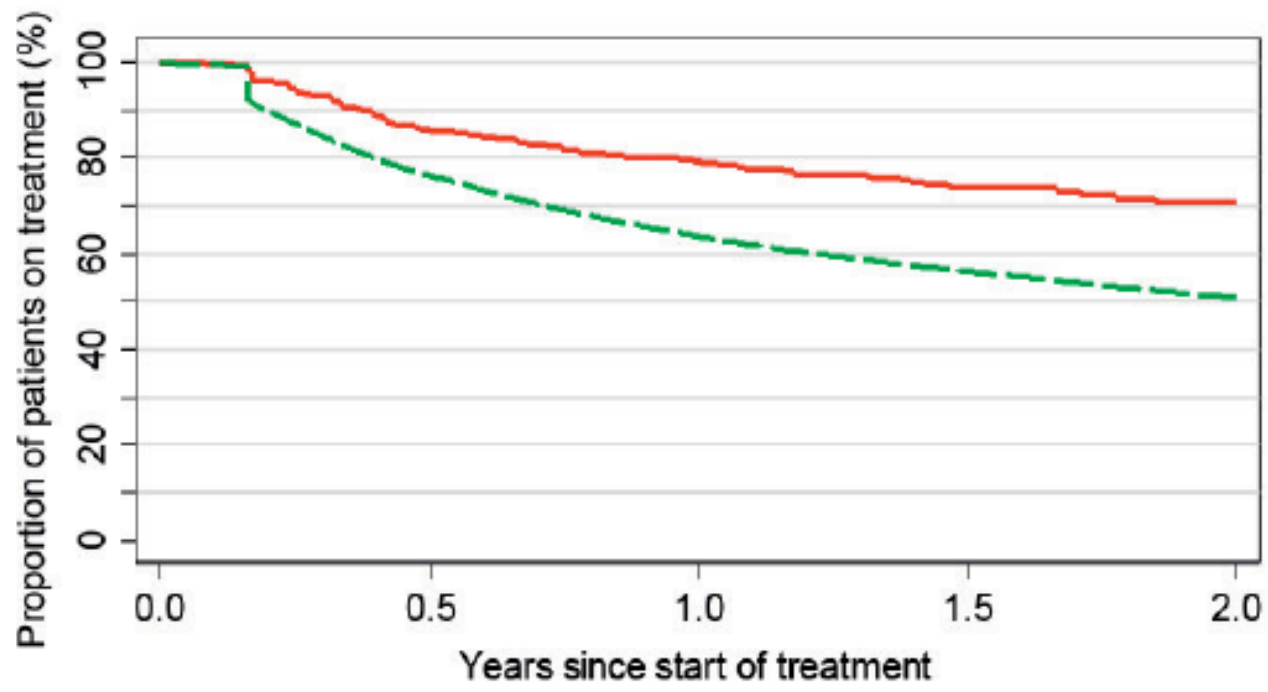
Use of OACs in AF Patients peaks at ~50%,
use declines with increasing risk





Despite NOAC Adoption and Ability to Switch NOACs, Adherence to Anticoagulation Remains a Challenge

~30% of NOAC patients stop taking any drug at 2 years



NOAC	914	651	342	139	41
VKA	12307	8453	5762	3915	2506

Challenge: Adherence and Major bleed rates with Novel Oral Anticoagulants (NOACs)



WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

Treatment	Study Drug Discontinuation Rate	Major Bleeding (rate/year)
Rivaroxaban ¹	24%	3.6%
Apixaban ²	25%	2.1%
Dabigatran ³ (150 mg)	21%	3.3%
Edoxaban ⁴ (60 mg / 30 mg)	33 % / 34%	2.8% / 1.6%
Warfarin ¹⁻⁴	17 – 28%	3.1 – 3.6%

For those that remain adherent, there is an annual compounding bleeding risk.

¹Connolly, S. NEJM 2009; 361:1139-1151 – 2 yrs follow-up (Corrected) ²Patel, M. NEJM 2011; 365:883-891 – 1.9 yrs follow-up, ITT ³Granger, C NEJM 2011; 365:981-992 - 1.8 yrs follow-up, ⁴Giugliano, R. NEJM 2013; 369(22): 2093-2104 – 2.8 yrs follow-up.

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

Non-Valvular Atrial Fibrillation (NVAF), Stroke, and Current Treatment Options



WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

- AFib is a growing problem associated with greater morbidity and mortality
 - 5x increased risk of stroke
 - 90% of clots formed in LA come from LAA
- Current treatments with warfarin or NOACs are effective, but many patients stop taking the medications
 - ~1 in 4 patients discontinue blood thinners after 2 years
- Anti-coagulation bleeding risk compounds over time; may not be viable as a long-term solution for some patients

Connection Between NVAF-Related Stroke and the Left Atrial Appendage



WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

AF Creates Environment for Thrombus Formation in Left Atrium

- Stasis-related LA thrombus is a predictor of TIA¹ and ischemic stroke².
- In non-valvular AFib, >90% of stroke-causing clots that come from the left atrium are formed in the LAA³.

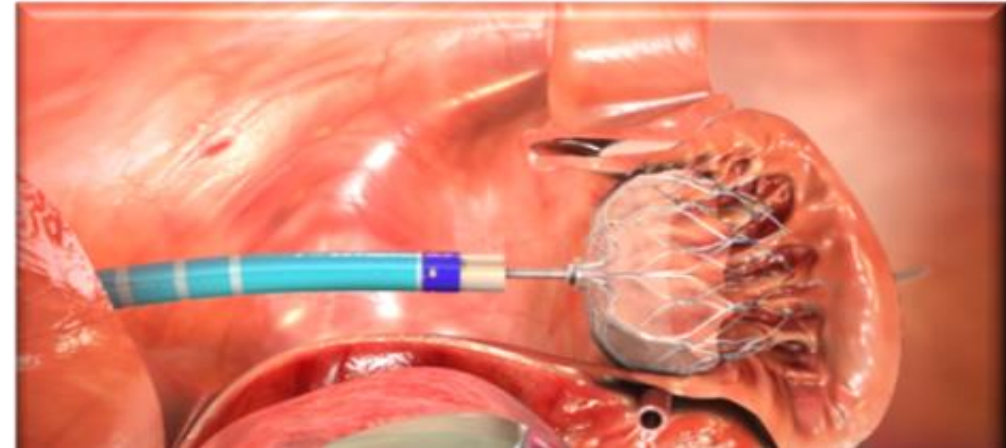


1. Stoddard et al. Am Heart J. (2003); 2. Goldman et al. J Am Soc Echocardiogr (1999)

3 Blackshear JL, Odell JA., *Annals of Thoracic Surg* (1996)

WATCHMAN LAAC Device: A One-Time Procedure

- One-time implant that does not need to be replaced
- Performed in a cardiac cath lab/EP suite by a Heart Team
- Transfemoral Access:
 - Catheter advanced to the LAA via the femoral vein
 - Does not require open heart surgery
- General anesthesia (typical)
- 1 hour procedure (typical)
- 1-2 day hospital stay (typical)



WATCHMAN FLX™

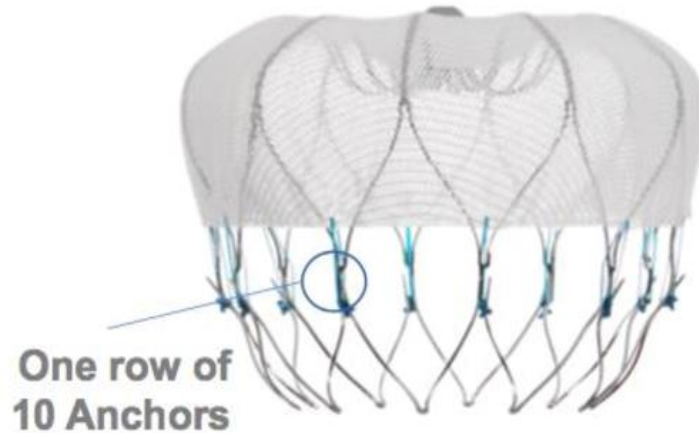
LEFT ATRIAL APPENDAGE CLOSURE DEVICE



Caution: The WATCHMAN FLX™ Left Atrial Appendage Closure Device is an investigational device and is not available for sale in the U.S. or Europe.

10 Strut Frame
Partial Recapture
Minimum LAA Depth = Ostium Diameter

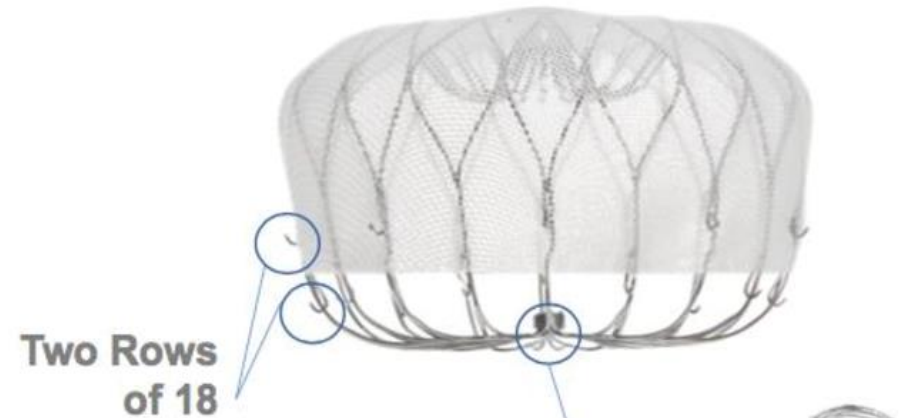
WATCHMAN™



'Straight' anchor

18 Strut Frame
Full or Partial Recapture
Minimum LAA Depth = ½ Device Size
PET fabric extended more distally

WATCHMAN FLX™



'J' anchor



Closed Distal End
Controlled Deployment

WATCHMAN is the Most Studied LAAC Device - Most Patients and Only One with Long-term Clinical Data



WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

Key Trials	N	Highlights
PROTECT AF¹ (2005-2008)	707	Prospective, randomized 2:1, non-inferiority trial of LAA closure vs. warfarin.
CAP² (2008-2010)	566	Prospective registry allowing continued access to the WATCHMAN Device and gain further information prior to PMA approval.
PREVAIL³ (2010-2012)	407	Prospective, randomized 2:1, non-inferiority trial to collect additional information on the WATCHMAN Device.
CAP2 (2012-2014)	579	Prospective registry allowing continued access to the WATCHMAN Device prior to PMA approval.
Total patients	>2,000	~6,000 Patient-Years of Follow-up

¹ Reddy, et al. JAMA. 2014 ;312(19): 1988-1998.; ² Reddy VY et al. Circulation. 2011; 123:417-424.

³ Holmes et al., JACC 2014;4(1): 1-11.

PROTECT AFib: WATCHMAN Disabling Stroke Reduction Superior to Warfarin



WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

Significant Reduction in Disabling Strokes

PROTECT AF	Event Rate (per 100 pt-yrs)			Posterior Probabilities, %	
	WATCHMAN N=463	Warfarin N=244	Rate Ratio (95% CrI)	Non- Inferiority	Superiority
Stroke (all)	1.5	2.2	0.68 (0.42, 1.37)	>99	83
Disabling	0.5	1.2	0.37 (0.15, 1.00)	>99	98
Non-disabling	1.0	1.0	1.05 (0.54, 2.80)	89	34

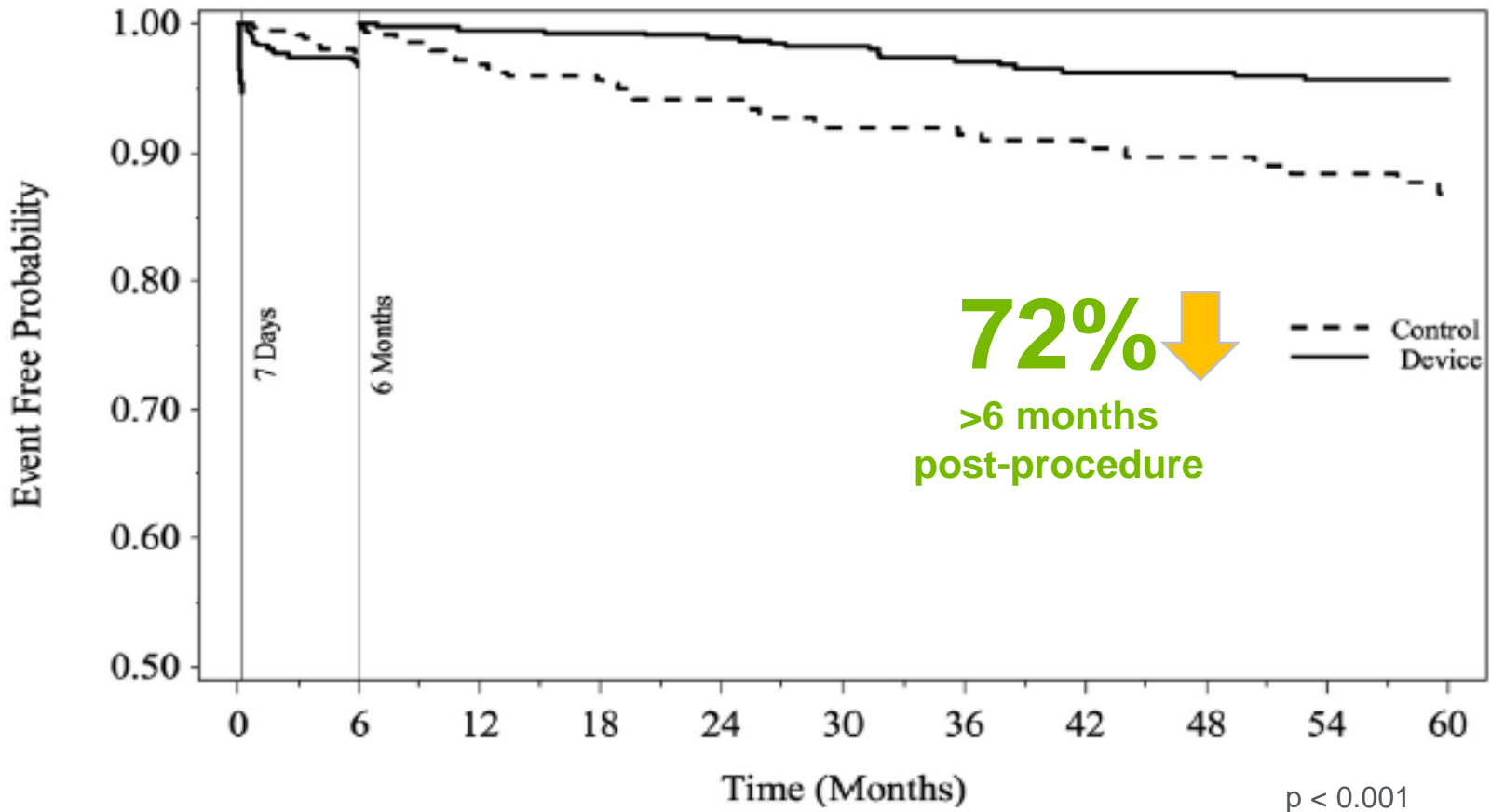
Disabling stroke defined as Modified Rankin Score 3-6

WATCHMAN Major Bleeding Reduction Superior to Warfarin 6-months Post Procedure



WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

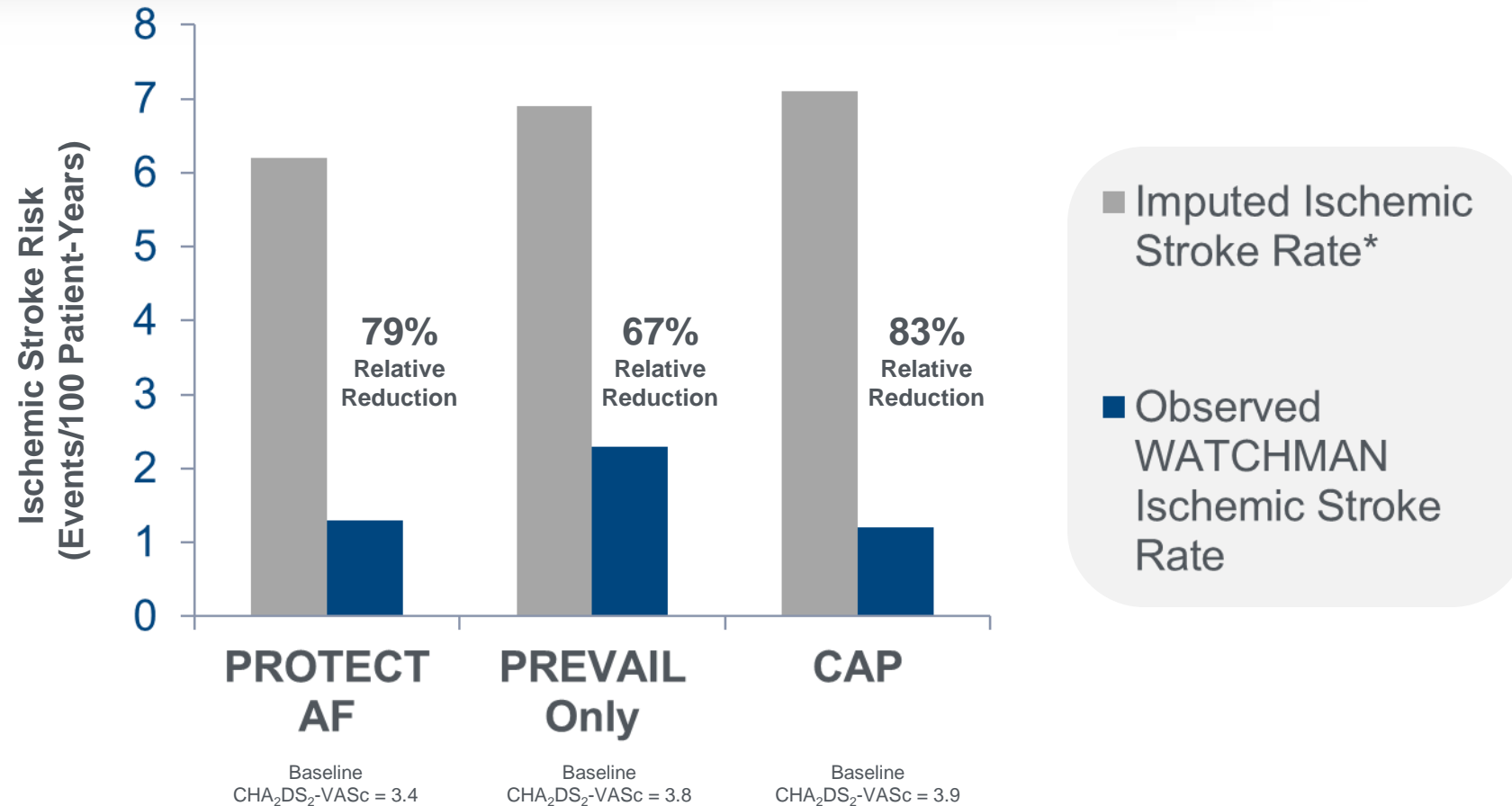
Freedom of Major Bleeding Over 3 Adjunctive Pharmacotherapy Intervals



WATCHMAN Reduced Ischemic Stroke Compared to No Therapy



WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE



* Imputation based on published rate with adjustment for CHA₂DS₂-VASc score (3.0); Olesen JB. Thromb Haemost (2011)

WATCHMAN is the Most Studied LAAC Device with Long-term Clinical Data



WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

Results		
Safety	WATCHMAN procedure is safe	95% implant success; ~4% complication rates ¹
Primary Efficacy	WATCHMAN comparable to warfarin	21% reduction in events (p=0.22) ³
All-Stroke	WATCHMAN comparable to warfarin	67% reduction in disabling strokes (P _s =98%) ² ; 78% reduction in hemorrhagic strokes (p=0.004) ³
CV / Unexp death	WATCHMAN superior to warfarin	52% reduction in events (p=0.006) ³
Major Bleeding	WATCHMAN comparable to warfarin; superior to warfarin post-procedure	52% reduction post-procedure (p=0.002); 72% reduction after 6-months (p=0.001) ⁴
Warfarin	WATCHMAN allows the majority of patients to discontinue warfarin	92% of patients discontinue after 45-days; 99% of patients discontinue after 1 year ⁵

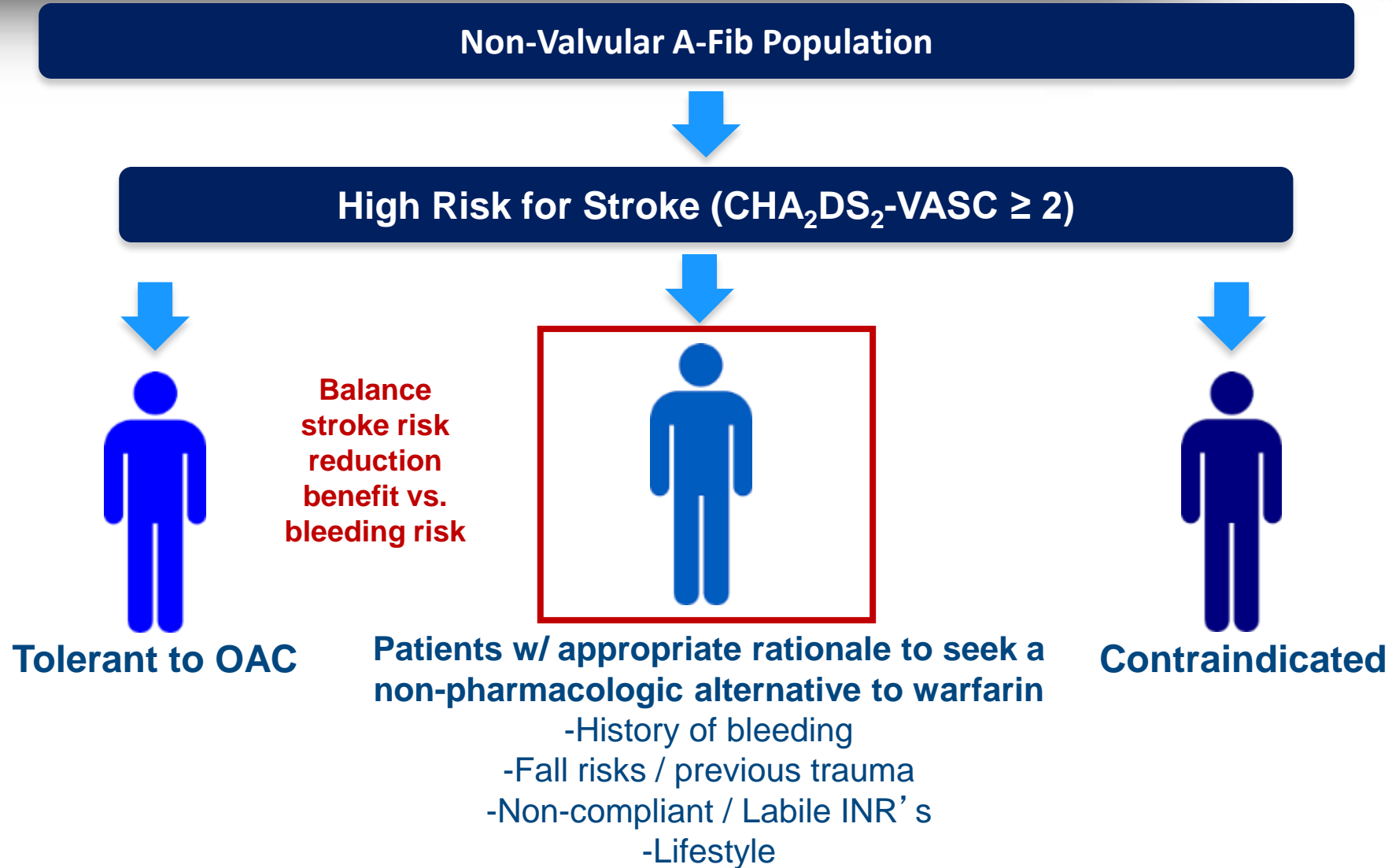
1. WATCHMAN FDA Panel Sponsor Presentation. Oct 2014.; 2 Reddy, et al. JAMA. 2014 ;312(19): 1988-1998.

3 Holmes, DR et al. JACC. 2015;65(24):2614-2623.; 4 Price, M. J., V. Y. Reddy, et al. JACC: CV Interv 2015; 8(15): 1925-1932; 5.Holmes, DR et al. JACC 2014; 64(1): 1-12.

Patient Populations



WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE





WATCHMAN™ Device Patient Selection

“Have an appropriate rationale to seek a non-pharmacologic alternative to Warfarin, taking into account the safety and effectiveness of the device compared to Warfarin”

- History of major bleeding while taking anticoagulation therapy
- Patient’s prior experience with OAC (if applicable):
 - *inability to maintain stable INR*
 - *inability to comply with regular INR monitoring and unavailability of an approved alternative OAC*
- Medical condition, occupation, or lifestyle placing patient at high risk of major bleeding secondary to trauma

CMS National Coverage Decision Criteria for Coverage



WATCHMAN™
LEFT ATRIAL APPENDAGE
CLOSURE DEVICE

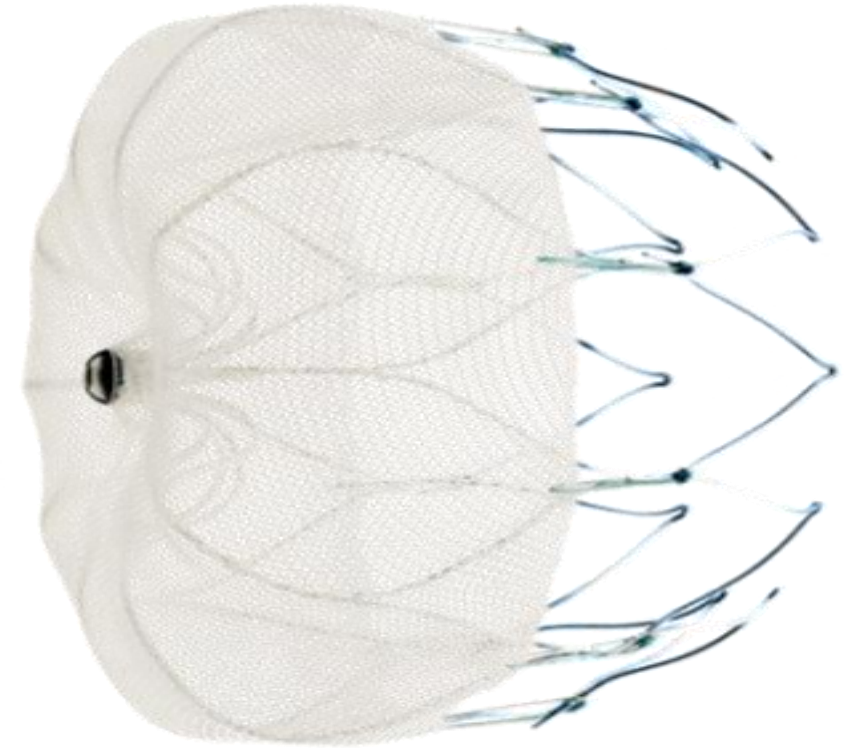
CMS will cover percutaneous LAAC implants when specific criteria are met:

Documented in
medical record

- Eligible patients must have a CHADS₂ score ≥ 2 or a **CHA₂DS₂-VASc score ≥ 3**
- Patients must be **suitable for short-term warfarin**, but deemed **unable to take long-term oral anticoagulation**
- **Documented evidence of a formal shared decision interaction between the patient and an independent non-interventional physician** using an OAC evidence-based decision tool
- *LAA Registry*: Patients must be enrolled in a prospective national registry
- *Operator requirements*: IC or EP or cardiovascular surgeon must have performed at least 25 transseptal punctures (TSP) through intact septum
 - Must maintain at least 25 TSP over a two year period (at least 12 are LAAC)
- *Facility Requirements*: The procedure must be furnished in a hospital with an established structural heart disease (SHD) and/or electrophysiology (EP) program

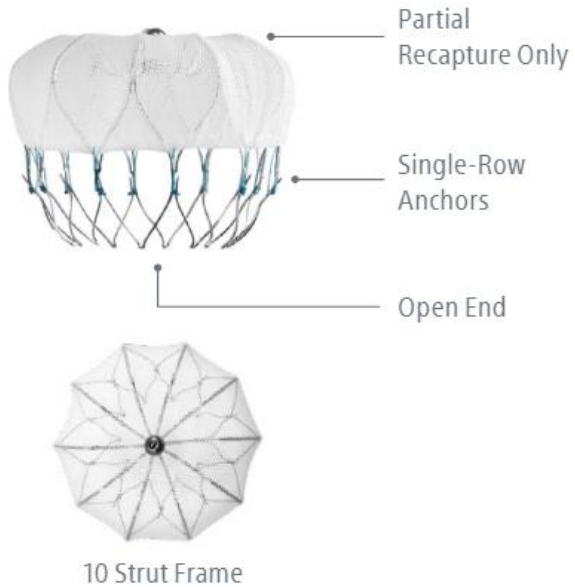
WATCHMAN Is A Safe, Effective, One-time Procedure for Appropriate NVAF Patients

- The WATCHMAN Implant has been proven to be a safe and effective alternative to long-term oral anticoagulants (OACs)¹
- Left atrial appendage closure (LAAC) with WATCHMAN may eliminate the need for long-term warfarin use in patients with non-valvular atrial fibrillation (NVAF) who have a reason to seek an alternative to OACs
- The WATCHMAN Implant has been proven to offer stroke risk reduction comparable to Warfarin—and also reduces the long-term risk of bleeding associated with Warfarin use.²



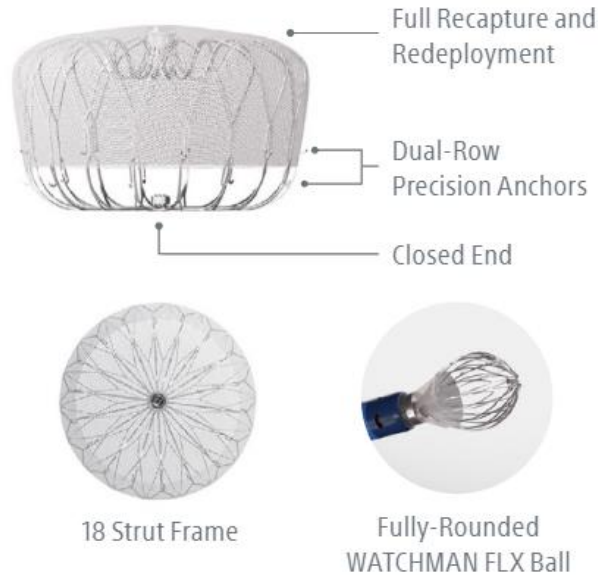
Boston Scientific is committed to continued innovation within the LAAC therapy

Legacy WATCHMAN™ LAAC Device Treatment Range 16.8– 30.5 mm Ostium Width



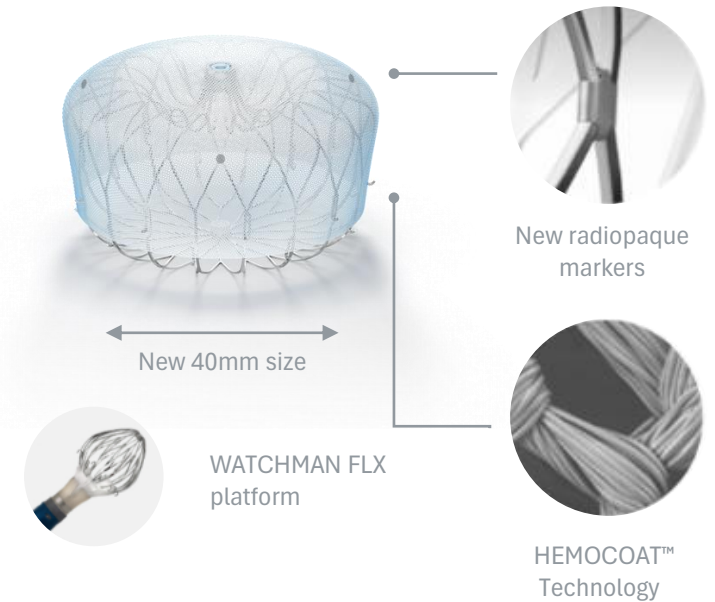
**FDA Approval
March 2015**

WATCHMAN FLX™ LAAC Device Treatment Range 14.0– 31.5 mm Ostium Width



**FDA Approval
July 2020**

WATCHMAN FLX™ Pro LAAC Device Treatment Range 14.0– 36.0 mm Ostium Width



**FDA Approval
September 2023**

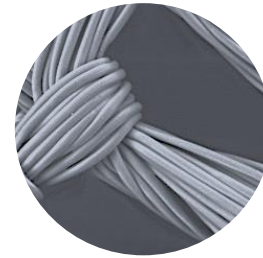
WATCHMAN FLX™ Pro

The next generation of WATCHMAN innovation

Built on the **proven performance** of the WATCHMAN FLX™ platform, WATCHMAN FLX™ Pro is designed to **improve the healing response and optimize placement**, while further expanding the treatable patient population.

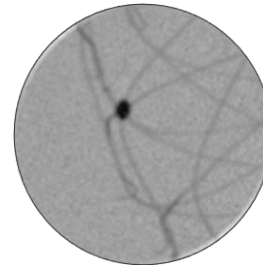


1. Saliba, W . et al. JACC EP, May 2023
2. Bench study performed under CT by Boston Scientific. Data on file.
3. BSC Data on File



Improved healing response

HEMOCOAT™ coating helps prevent thrombus formation and results in less inflammation, leading to **faster, more complete device healing** as demonstrated in a challenging pre-clinical model.¹



Optimized device placement

Radiopaque markers help to position, anchor and stabilize the device with 57% greater visibility, **optimizing sealing performance through better device placement.**²



More patients treated

New 40mm device size **expands the treatable patient population** by 6%.³

WATCHMAN FLX™ Pro Implant Animation

<https://vimeo.com/bostonscientific/wmflxpro>

Thank You!

Questions?

 Boulder Community Health Foundation
Over 40 Years of Community Impact

Enhancing the quality and availability
of health care in our community

COMMUNITY

We believe everyone should have a fair and just opportunity to reach their full health potential, both physically and mentally.

PATIENTS

We believe providing the community with the highest value in health care requires an innovative, patient-centered environment.

WORKFORCE

We believe it's imperative to invest in the professional growth and physical and mental health of BCH's greatest asset—the staff and physicians providing care to the community.

Learn more at bch.org/foundation



Innovative Treatments for Atrial Fibrillation

Maria Anderson, MD

Oussama Lawand, MD, FHRS

Srini Iyengar, MD

Boulder Heart

720-453-2822