# Beyond Anticoagulants: The Watchman Solution for Left Atrial Appendage Closure

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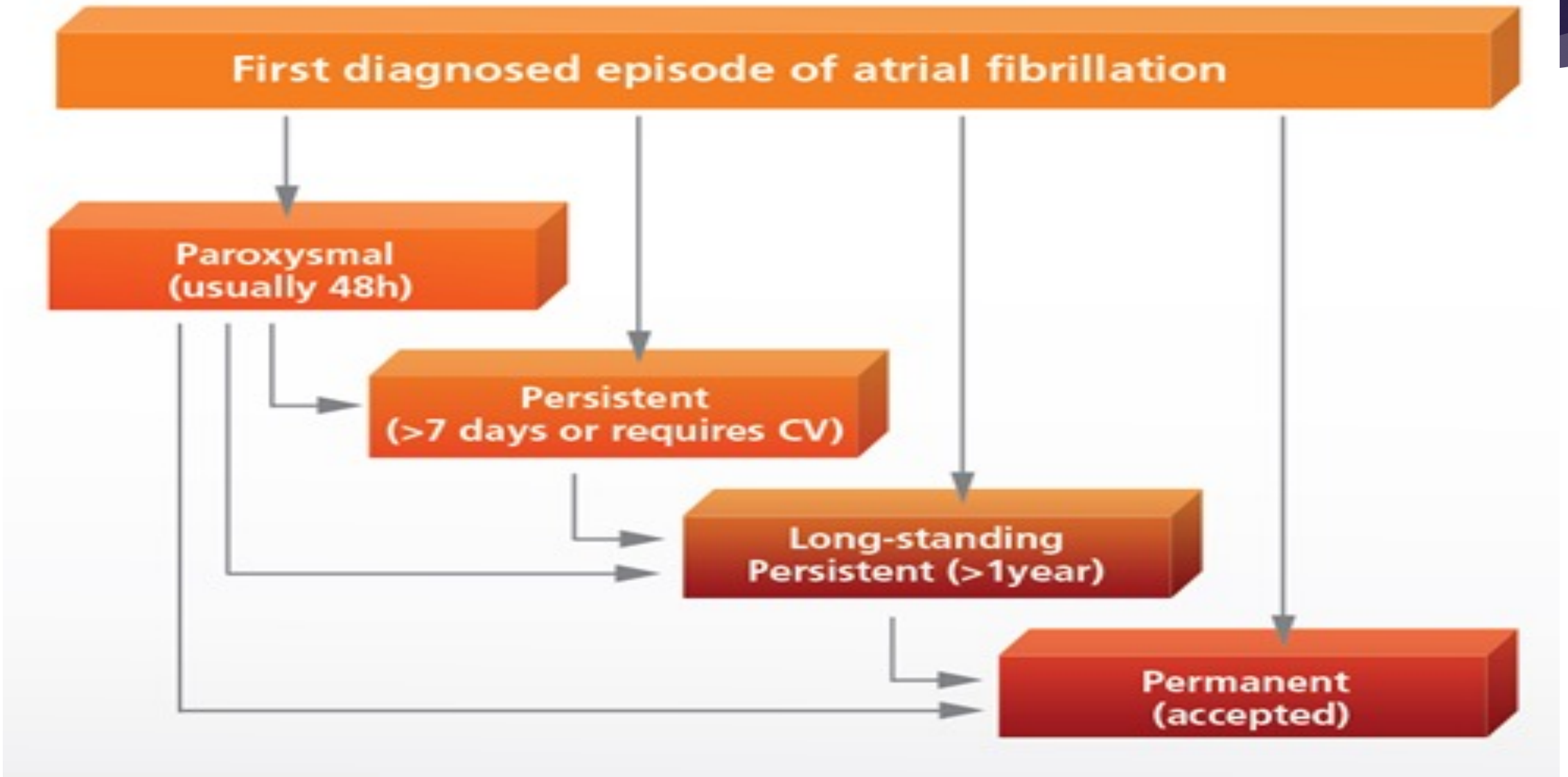
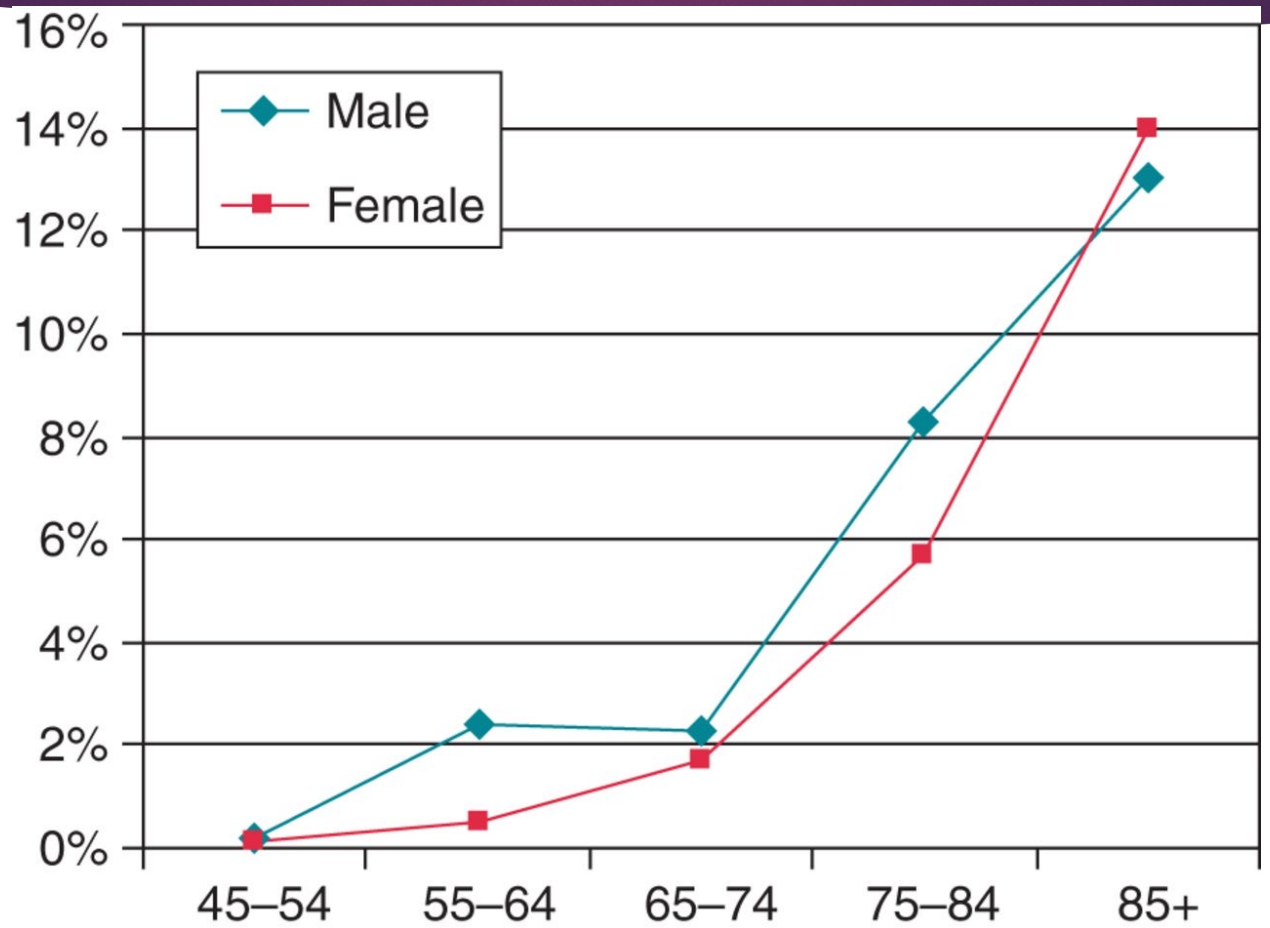
# Disclosures: None

# Lecture Outline

- AFib Overview
  - Scope of Issue/LAA Anatomy
- AF CVA Risk
- Watchman Clinical Studies
- Watchman: Endovascular Procedure
- Patient Candidates
- Guidelines


First diagnosed episode of atrial fibrillation
Paroxysmal (usually 48h)
Persistent (>7 days or requires CV)
Long-standing Persistent (>1year)
Permanent (accepted)

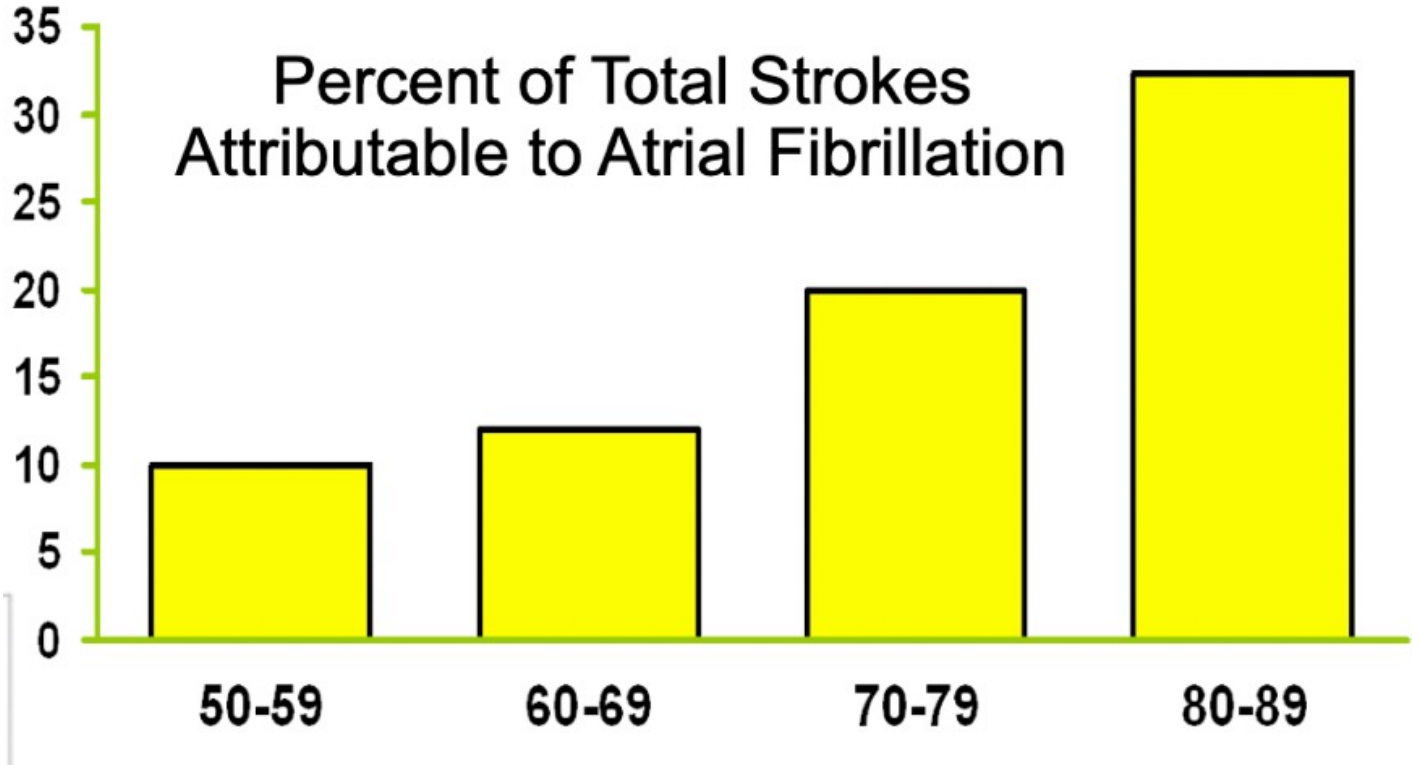
# Prevalence




*Europace*, Volume 14, Issue 11, November 2012, Pages 1553–1559

# AFIB & CVA

500,000 strokes / year in US
Up to 20% of CVA occur in patients with atrial fibrillation




J Family Community Med

. 2019 May-Aug;26(2):92–97

# AFIB Related Disability

## Stroke

**#1** cause of **adult disability** worldwide[1]

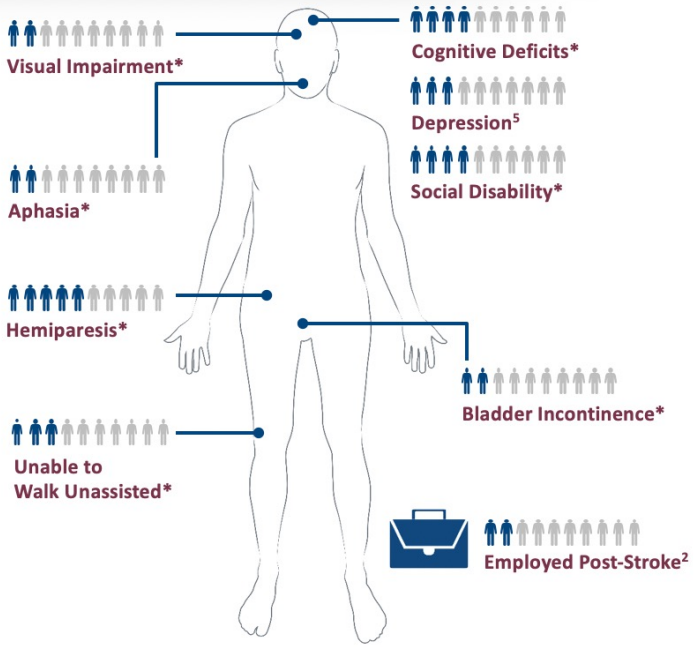
## AF-related Stroke

**1.5X** higher **disability**[3**]

**2X** higher **mortality**[3**]

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

*at 6 months post-stroke[4]
**compared with stroke patients without AF



# Why Do We Have Left Atrial Appendage?

# Why Do We Have Left Atrial Appendage?

- LAA vestigial structure similar to the appendix
- The left atrial appendage (LAA) is a small, pouch-like structure in the heart's left atrium that's generally considered nonfunctional
- Neurohormonal function

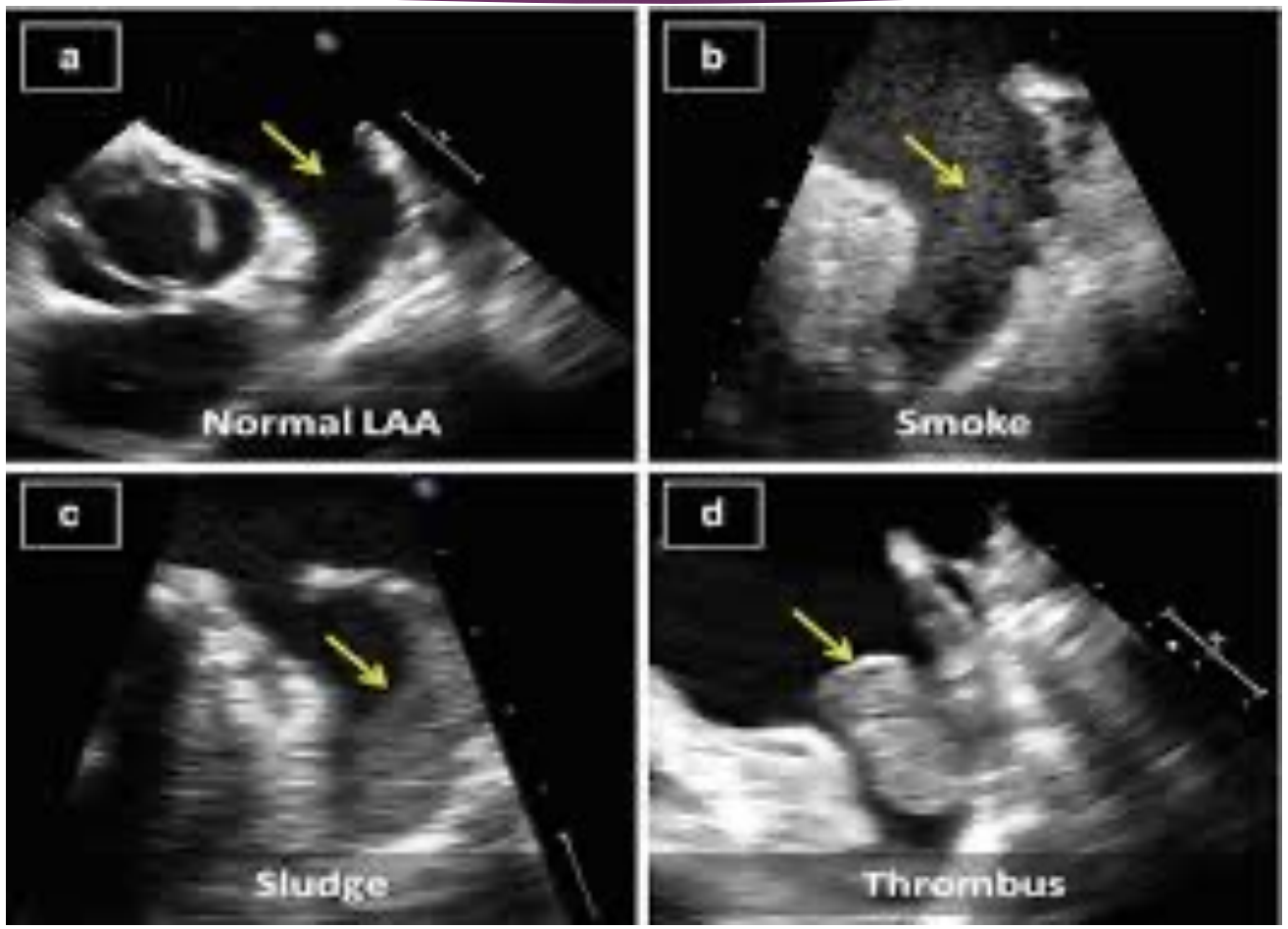
# LAA Function

- Neurohormonal: ↑ ANP

- Reservoir :

The LAA may play a role in regulating intravascular volume and left atrial pressure. However, people can function well without it

# A Continuum of Increasing Embolic Risk



# LAA & Thromboembolic Events

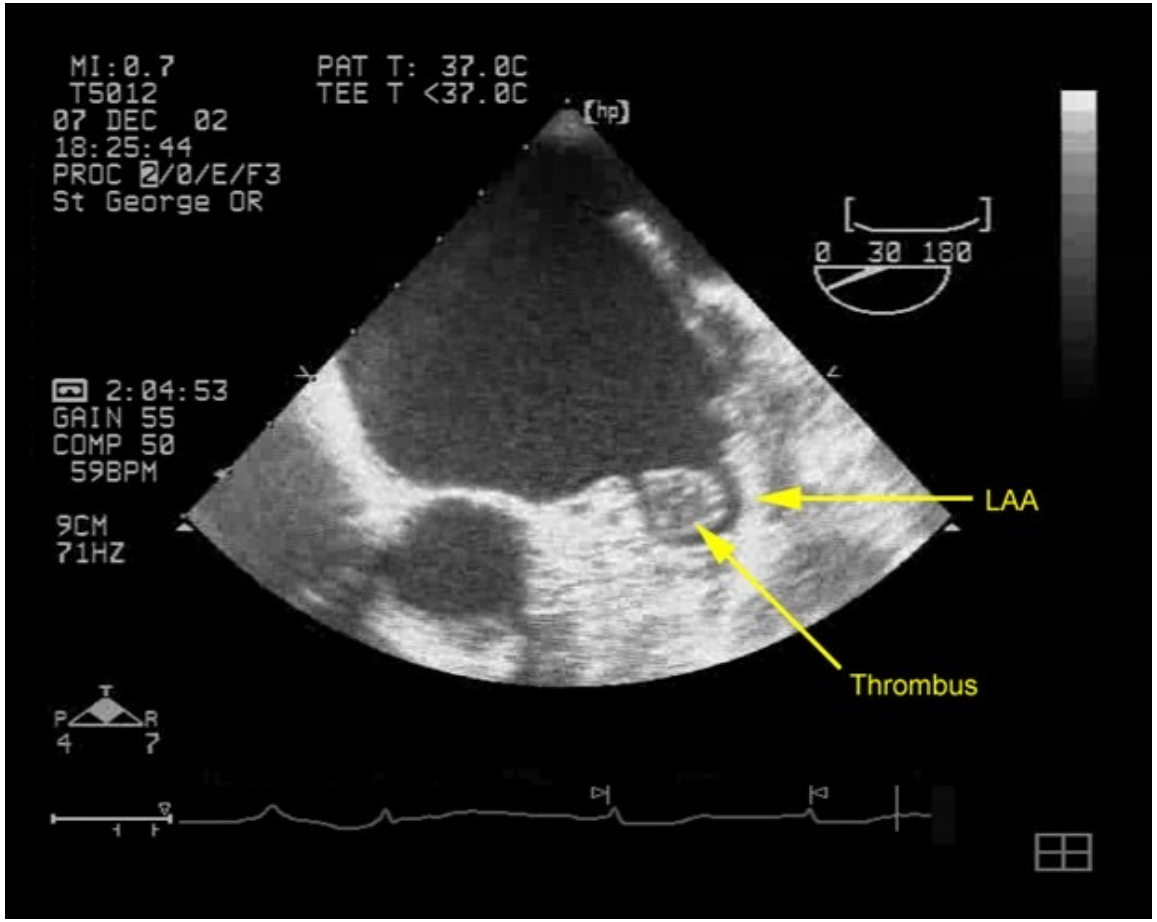
**AF Creates Environment for Thrombus Formation in Left Atrium**

- Stasis-related LA thrombus is a predictor of TIA[1] and ischemic stroke[2].
- In non-valvular AF, >90% of stroke-causing clots that come from the left atrium are formed in the LAA[3].

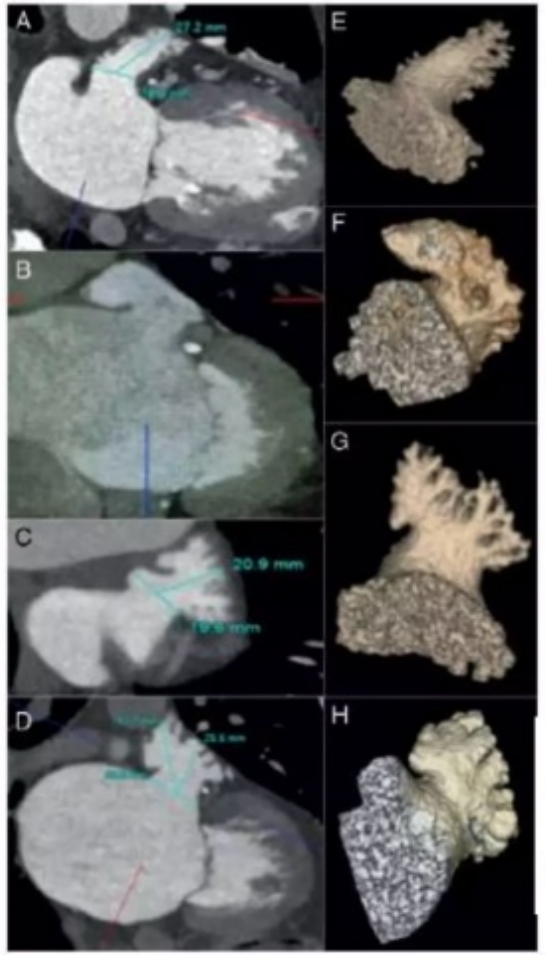

1. Stoddard et al. Am Heart J. (2003); 2. Goldman et al. *J Am Soc Echocardiogr* (1999)
3 Blackshear JL. Odell JA., *Annals of Thoracic Surg* (1996)

# LAA Function


# LAA Clot


MI:0.7
T5012
07 DEC 02
18:25:44
PROC 2/0/E/F3
St George OR
PAT T: 37.0C
TEE T <37.0C
0 30 180
2:04:53
GAIN 55
COMP 50
59BPM
9CM
71HZ
LAA
Thrombus

# LAA Anatomy: 4 Types



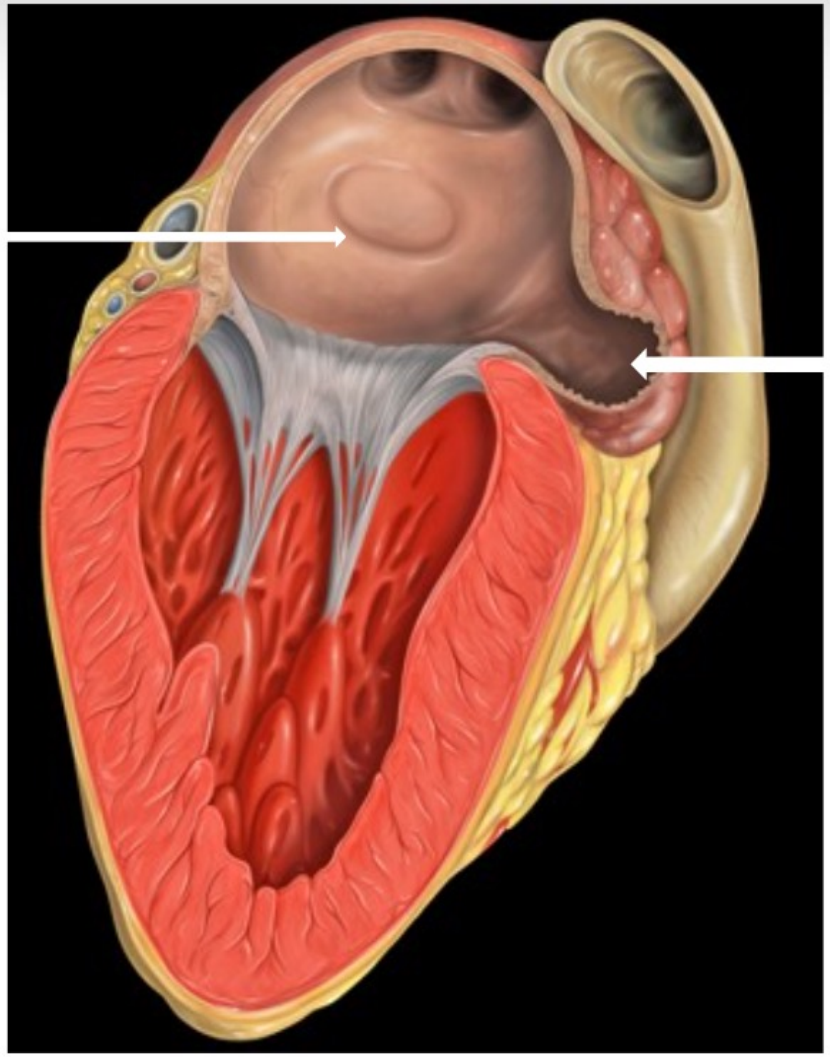

Windsock

Chicken Wing

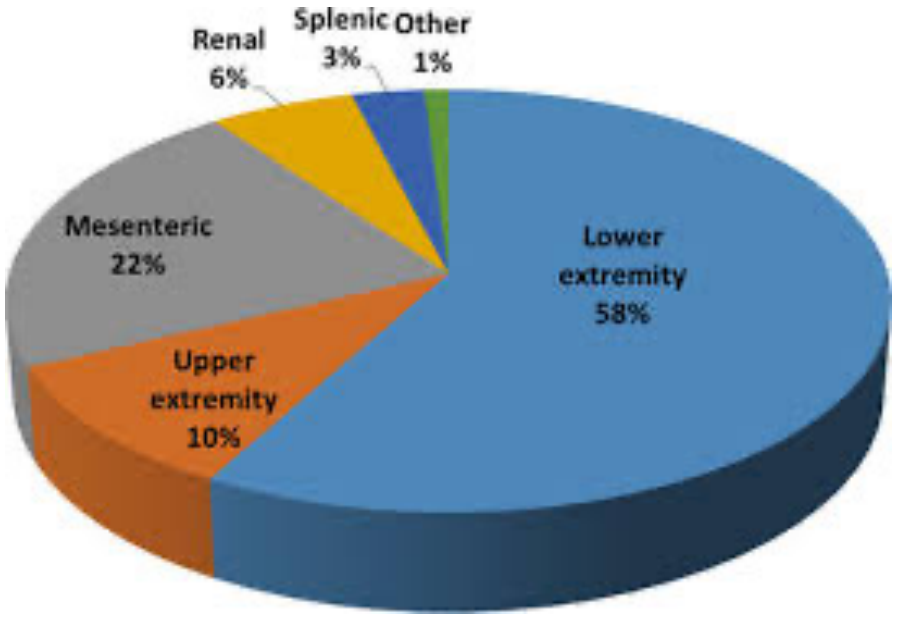
Cactus

Cauliflower

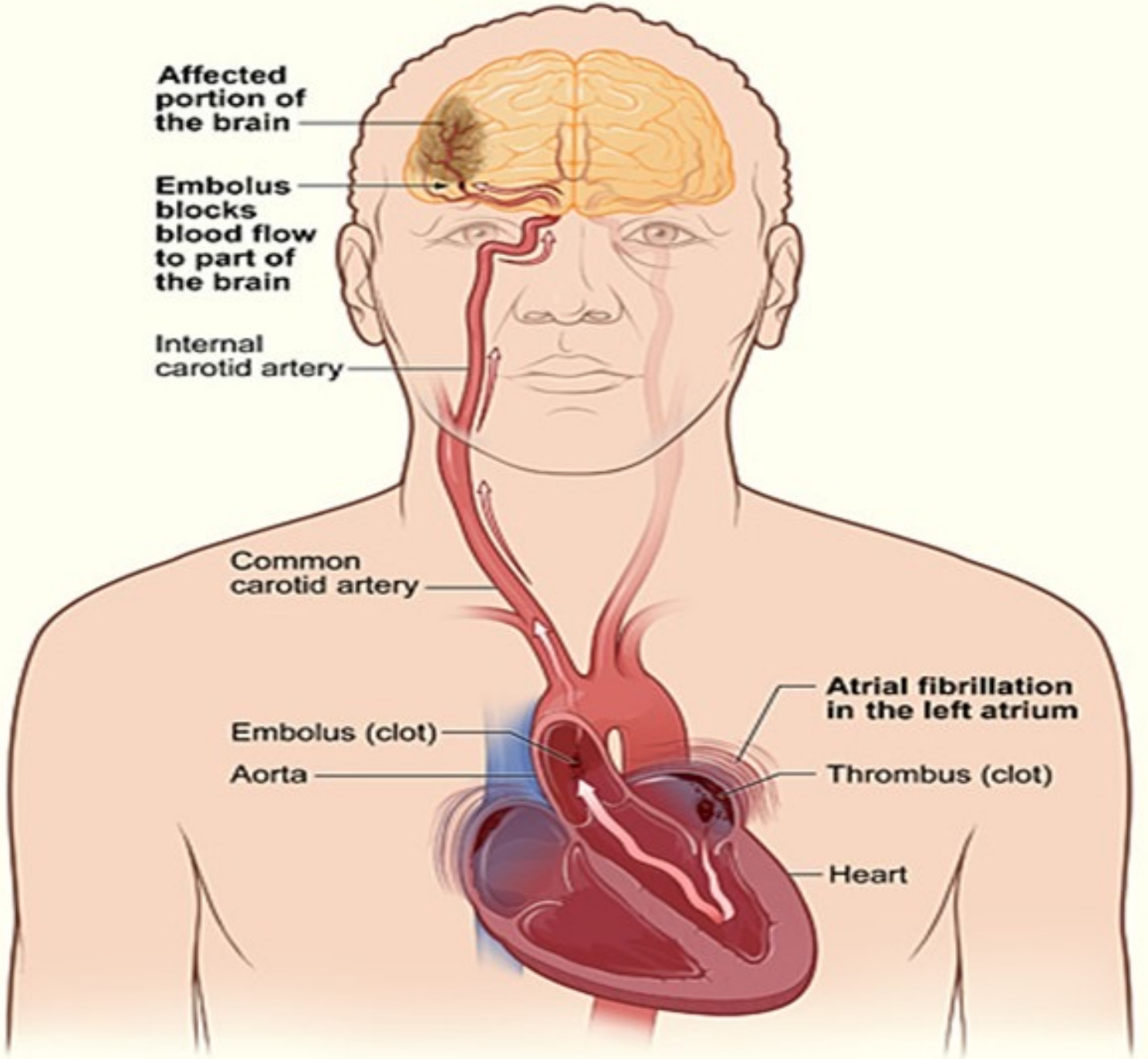
# Why LAA Occlusion?



# Systemic Embolism

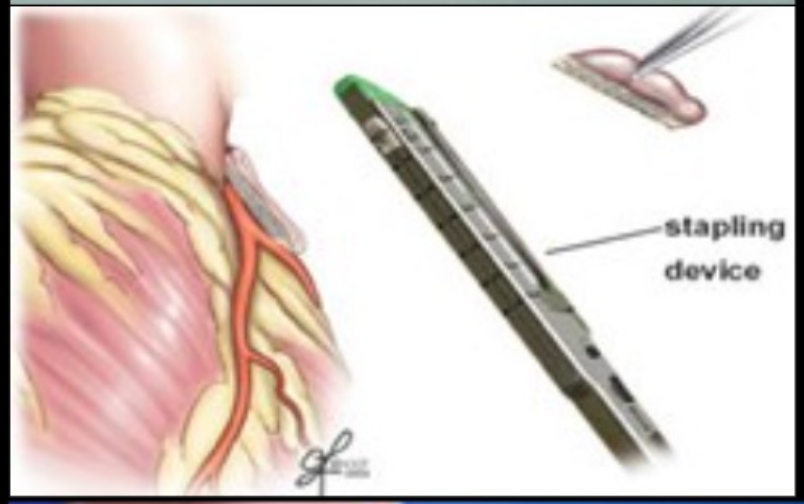



Extra-Cranial Embolism



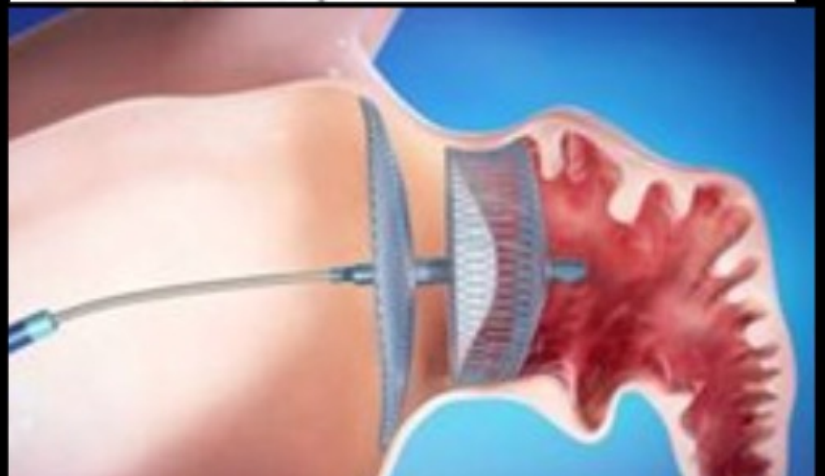

## Medical Management: Anticoagulant

- Effective: 67% stoke risk reduction(1)
- Narrow therapeutic window for proper dose
- Contraindicated in 14-47% of patients at risk of stroke (2)
- Major complication: bleeding




## Surgical Excision (Appendectomy)

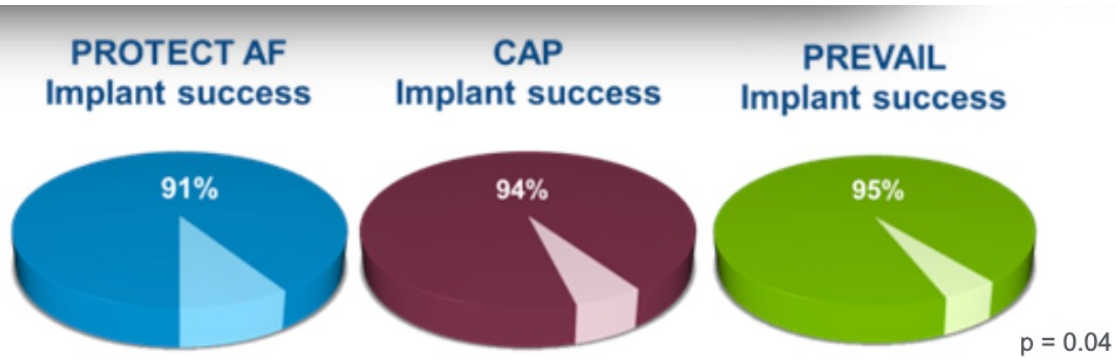
- Residual shunt: 10% (3)
- Inconsistent outcomes due to incomplete exclusion;
- Can create pouch with stagnant blood flow (4,5)
- High invasiveness



## Transcatheter Device Closure

- Minimally invasive nature
- Designed for percutaneous closure of the LAA in prevention of clot embolization that may form in the LAA
- Intended as an alternative to warfarin therapy for

# Watchman Implant Success




Implant success defined as deployment and release of the device into the left atrial appendage

**Warfarin Cessation**

| Study | 45-day | 12-month |
|---|---|---|
| PROTECT AF | 87% | >93% |
| CAP | 96% | >96% |
| PREVAIL | 92% | >99% |

**PREVAIL Implant Success**

No difference between new and experienced operators

Experienced Operators
- n=26
- 96%

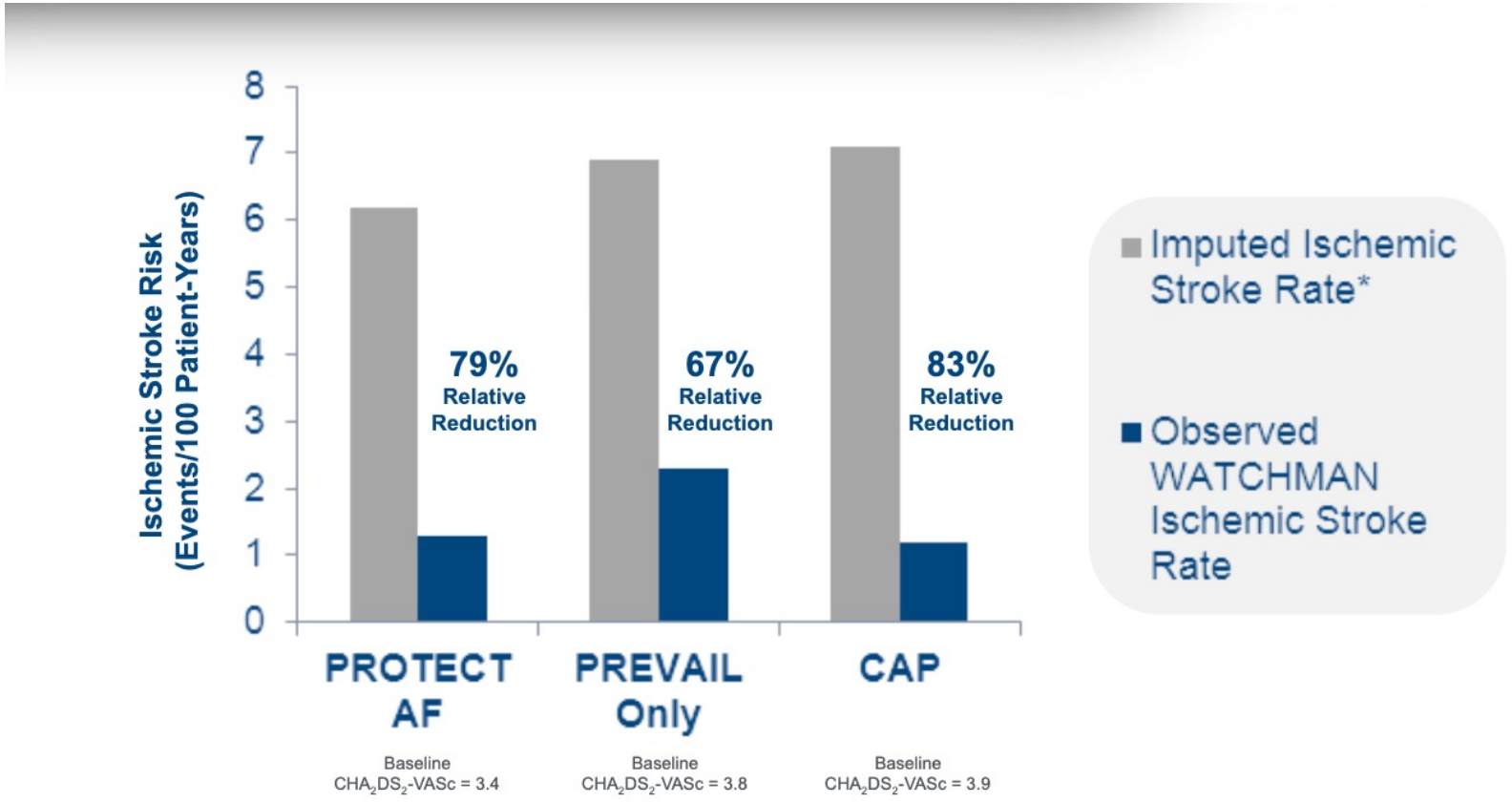
New Operators
- n=24
- 93%

p = 0.28

PROTECT AF and CAP: Reddy, VY et al. Circulation. 2011;123:417-424.
PREVAIL: Holmes, DR et al. *JACC* 2014; 64(1):1-12.

SH 286002 AB MAR 2015

# Watchman versus No Therapy

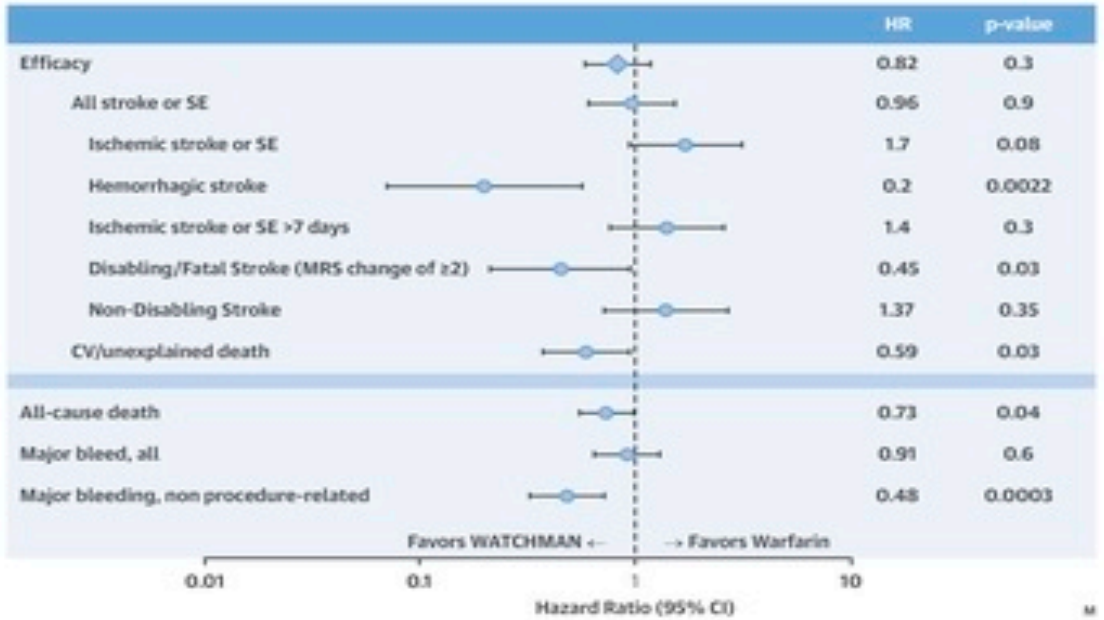


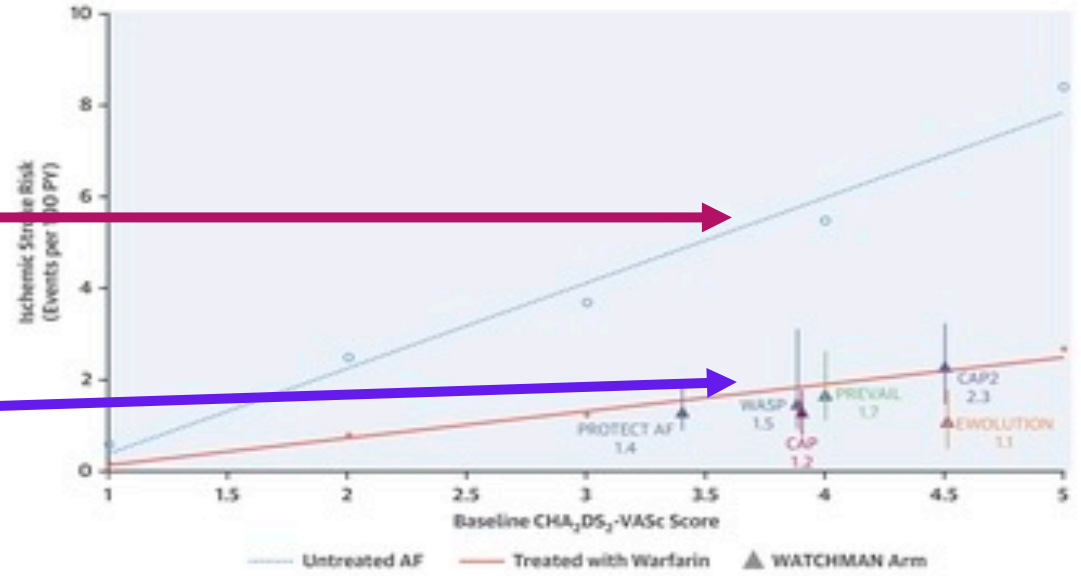
# Meta-Analysis of WATCHMAN Trials

No Therapy

WATCHMAN or Warfarin

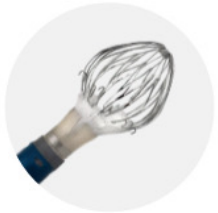
**CENTRAL ILLUSTRATION: Stroke Prevention in Nonvalvular Atrial Fibrillation With LAA Closure**



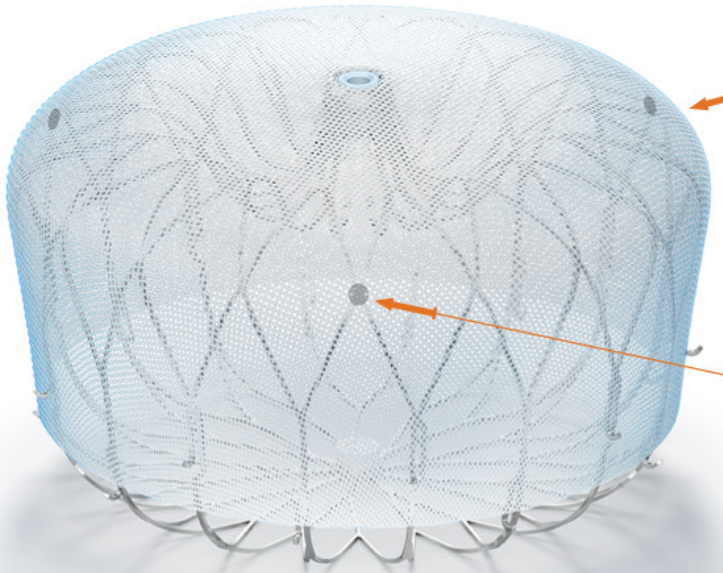




Reddy, V.Y. et al. J Am Coll Cardiol. 2017;70(24):2964-75.

# WATCHMAN DEVICE



**WATCHMAN FLX™ Platform**
with proven safety &
procedural performance

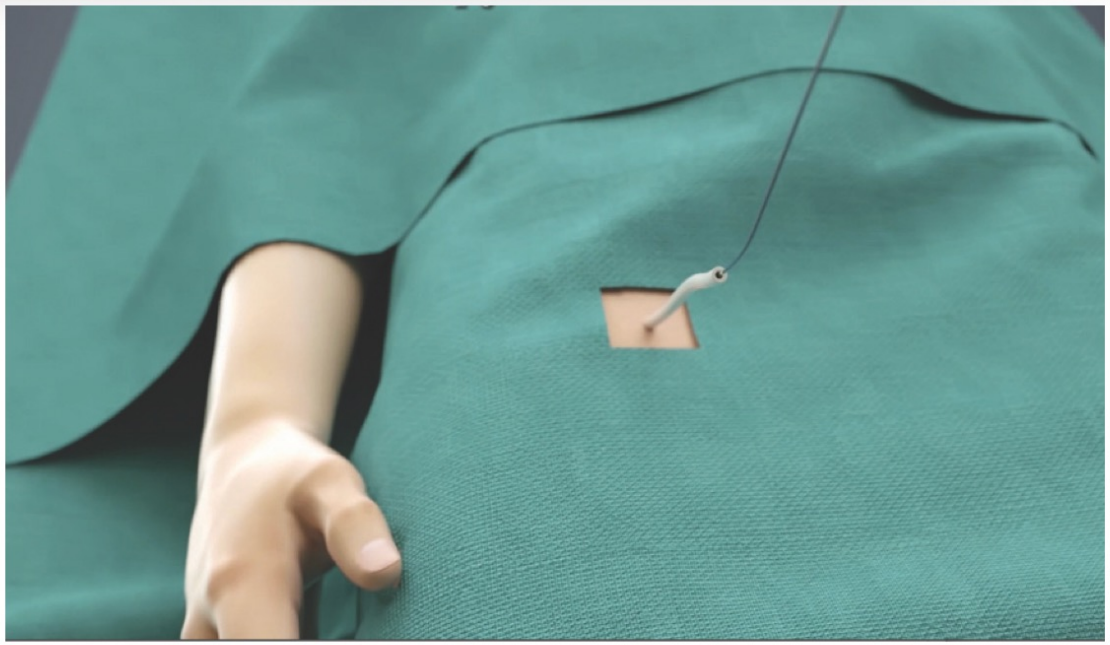


**New 40mm device**
to treat the widest range of anatomies

**HEMOCOAT Technology**
a hemocompatible coating to
promote faster, more complete
endothelialization

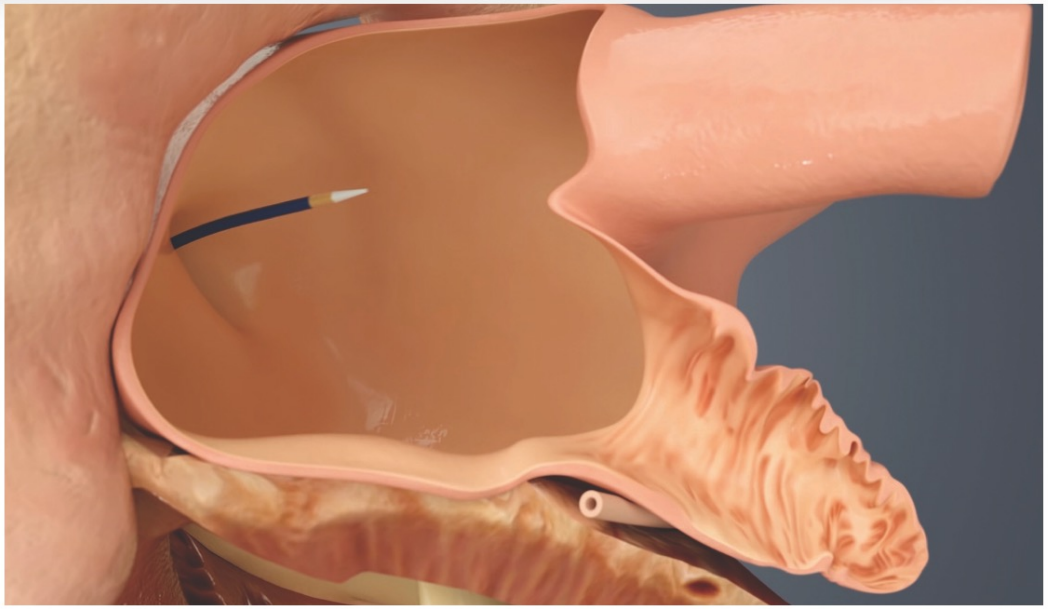
**Three new radiopaque markers**
help position and anchor device
with a new level of visual accuracy

# WATCHMAN Procedure



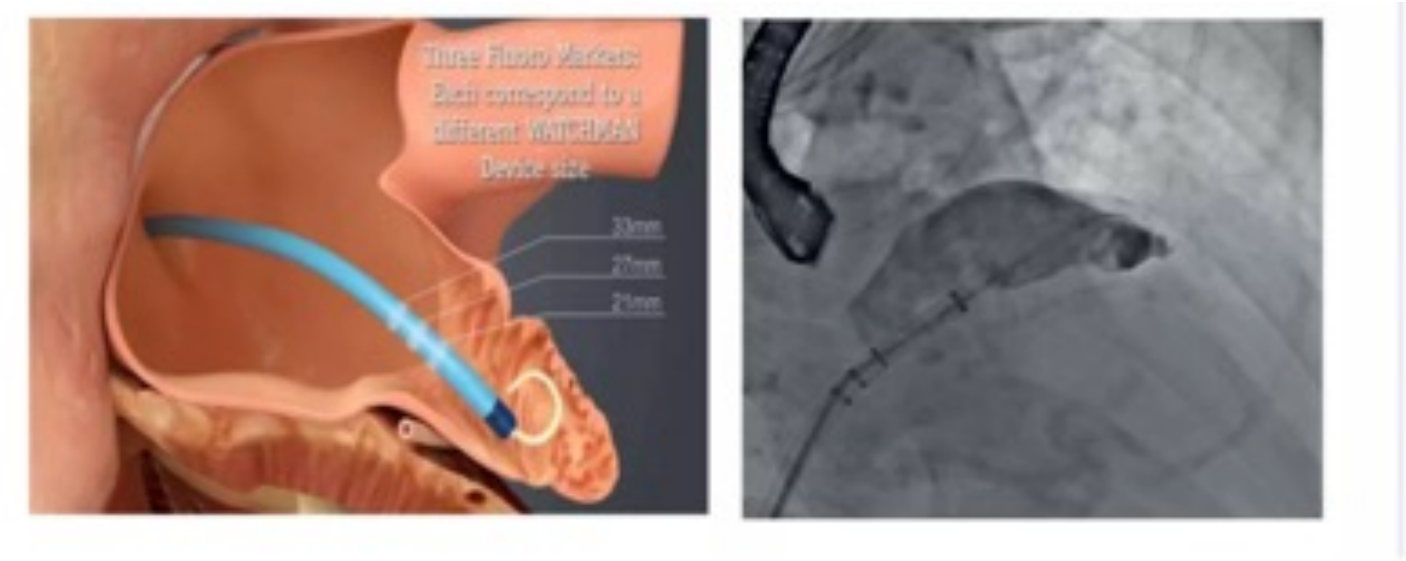
Using a standard percutaneous technique, a guidewire and vessel dilator are inserted into the femoral vein.

# WATCHMAN Procedure



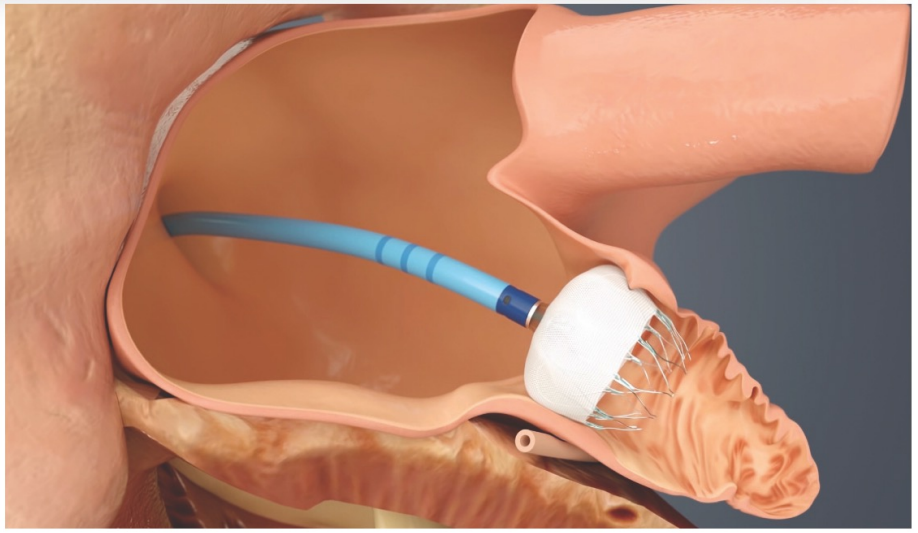
The interatrial septum is crossed using a standard transseptal access system and the procedure is performed with fluoroscopy and transesophageal echocardiography (TEE)

# WATCHMAN Procedure



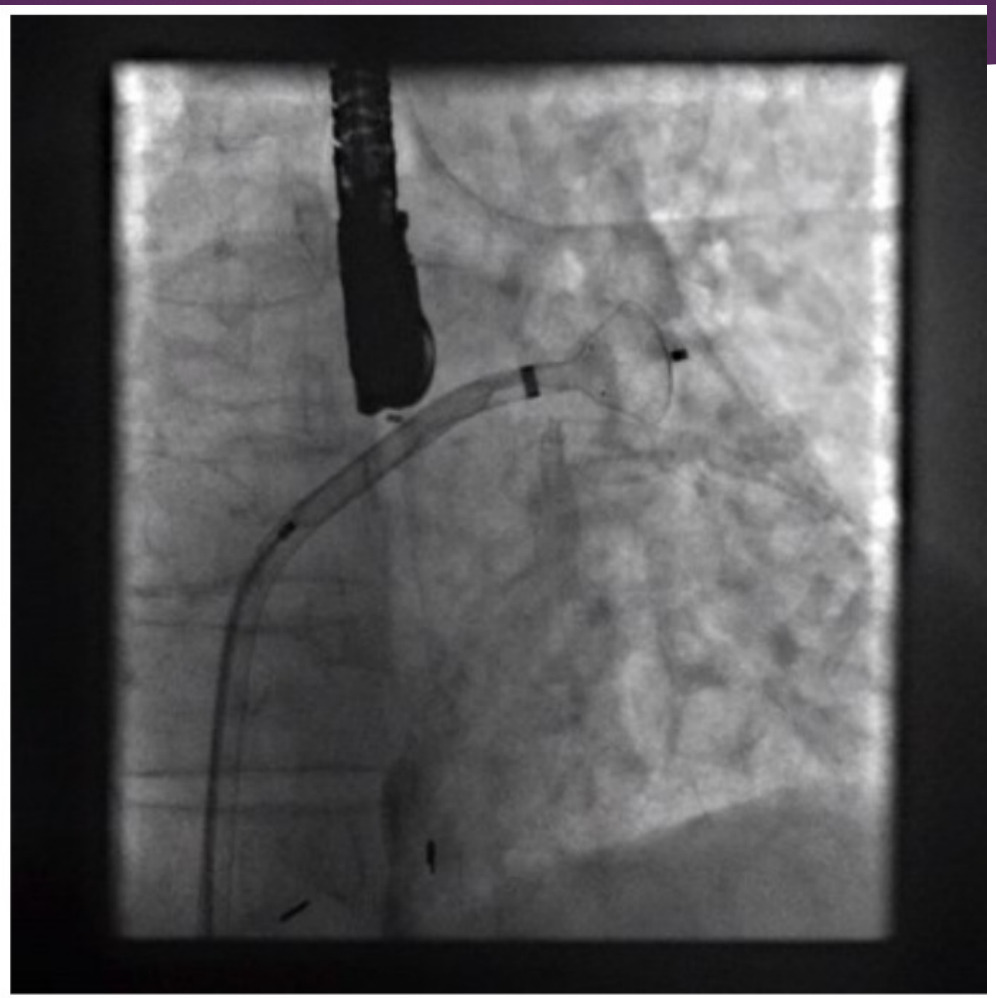
-14-French sheath placed in LAA over a pigtail catheter

# WATCHMAN Procedure



WATCHMAN is then deployed and released in the LAA.

# WATCHMAN Procedure



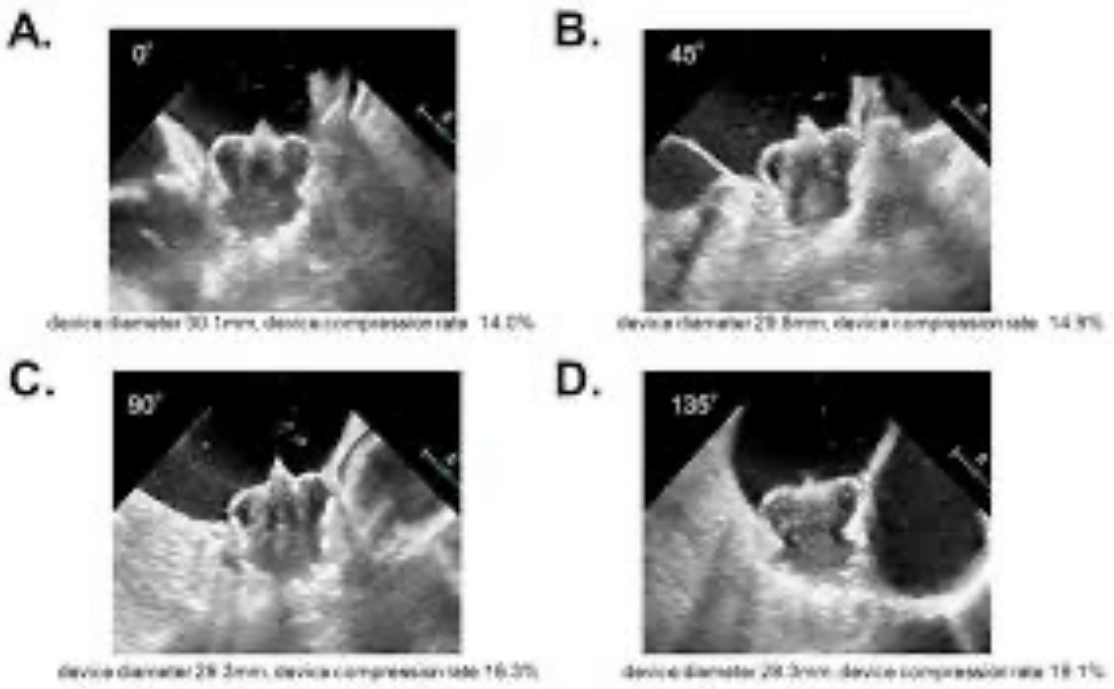
# WATCHMAN Procedure

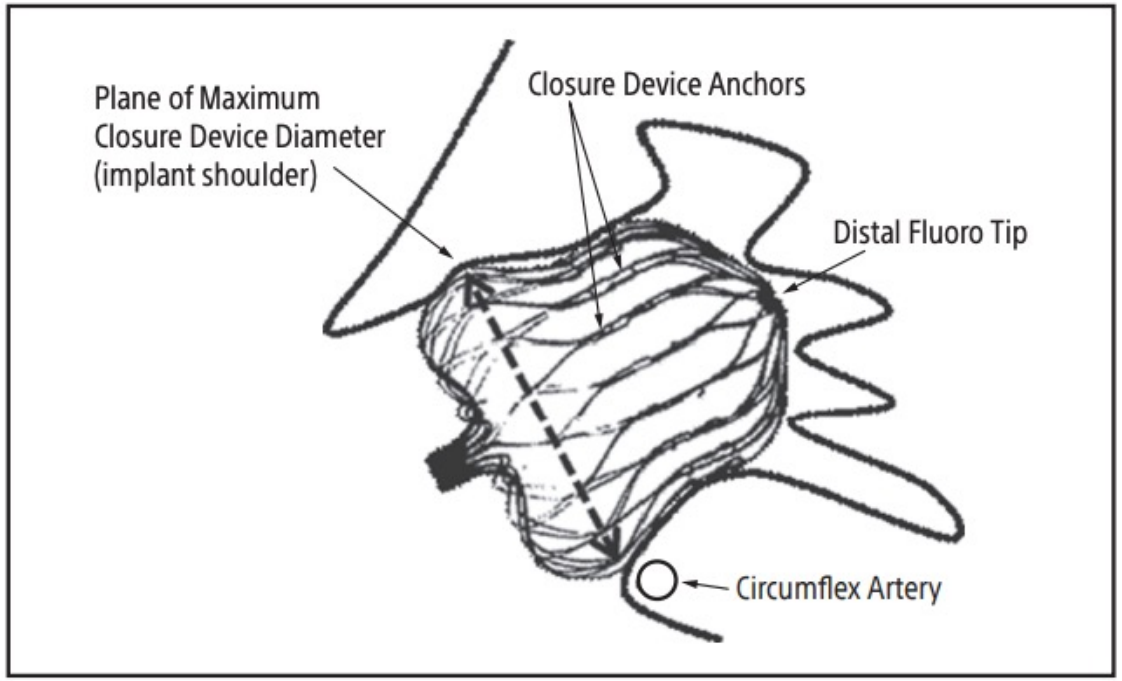
Heart tissue grows over the WATCHMAN Implant, and the LAA is permanently sealed after approximately 45 days

# WATCHMAN : TEE View

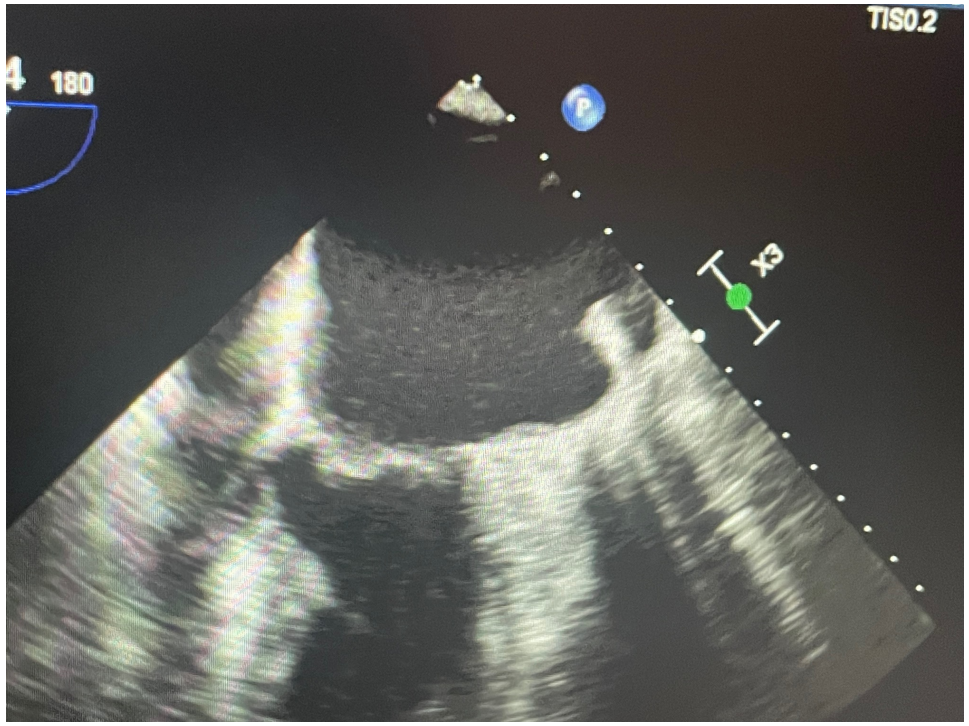
# WATCHMAN : TEE View

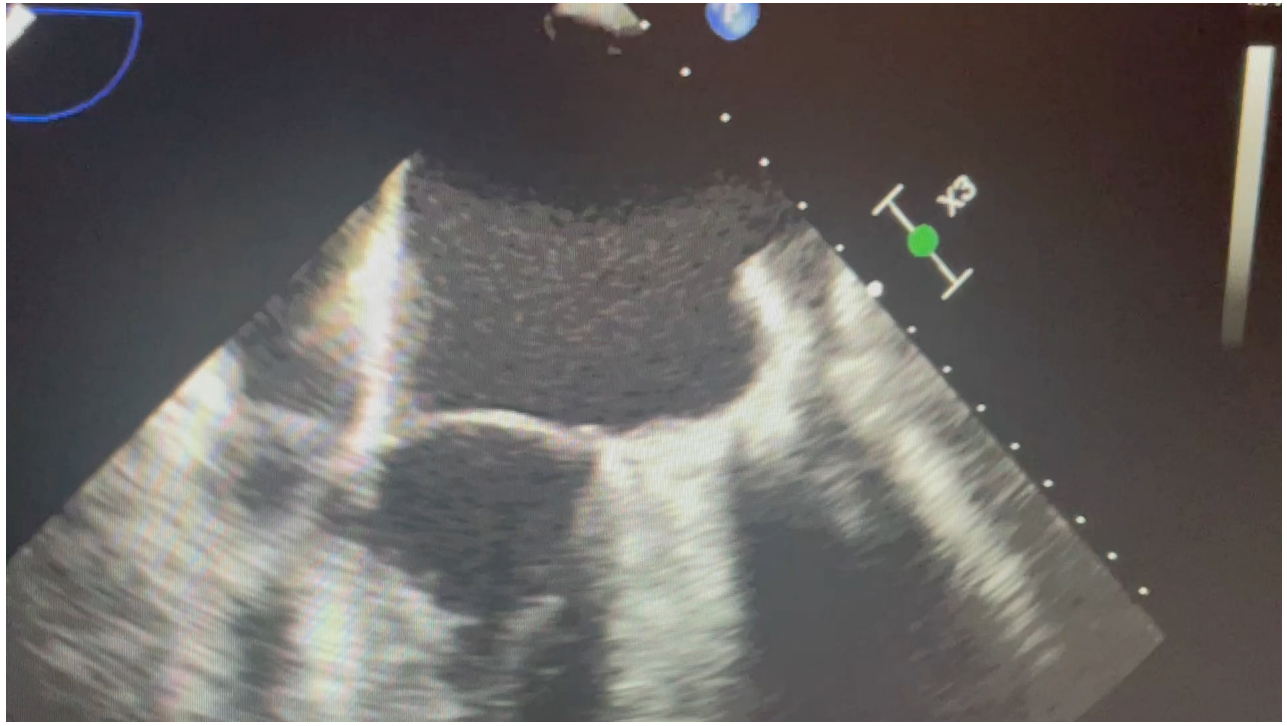
# Post Deployment Assessment



# TEE: Post Surgical Excision



# Atrial Fibrillation & Anticoagulation

- High Prevalence
- High Cost
- Low Medication Adherence
- Poor Monitoring Behavior
- Poor Patient Understanding

Kneeland PP: Patient Prefer Adherence 2010;4:51-60

# Anticoagulation: Discontinuation and Bleeding Rates

| Treatment | Study Drug Discontinuation Rate% | Major Bleeding % /per year |
|---|---|---|
| Rivaroxaban | 24% | 3.6% |
| Apixaban | 25% | 2.1% |
| Dabigatran | 33% | 2.8% |
| Warfarin | 17-28% | 3.1-3.6% |

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

# Risk Stratification

## $CHA_2DS_2VASc$ 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 |

# WATCHMAN Candidates

**Contra-indicated** (Cannot take any OAC)

**Bleeder** (Previous bleed but on OAC)

**Future Bleeder** (No prior bleeds but high-risk / include fall risk)

**Non-Compliant** (tolerant but not taking OAC)

**Lifestyle** (Patient prefers device over OAC)

# AFIB: Anticoagulation

Stroke Reduction


Bleeding

# CMS Coverage

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

Documented in medical record

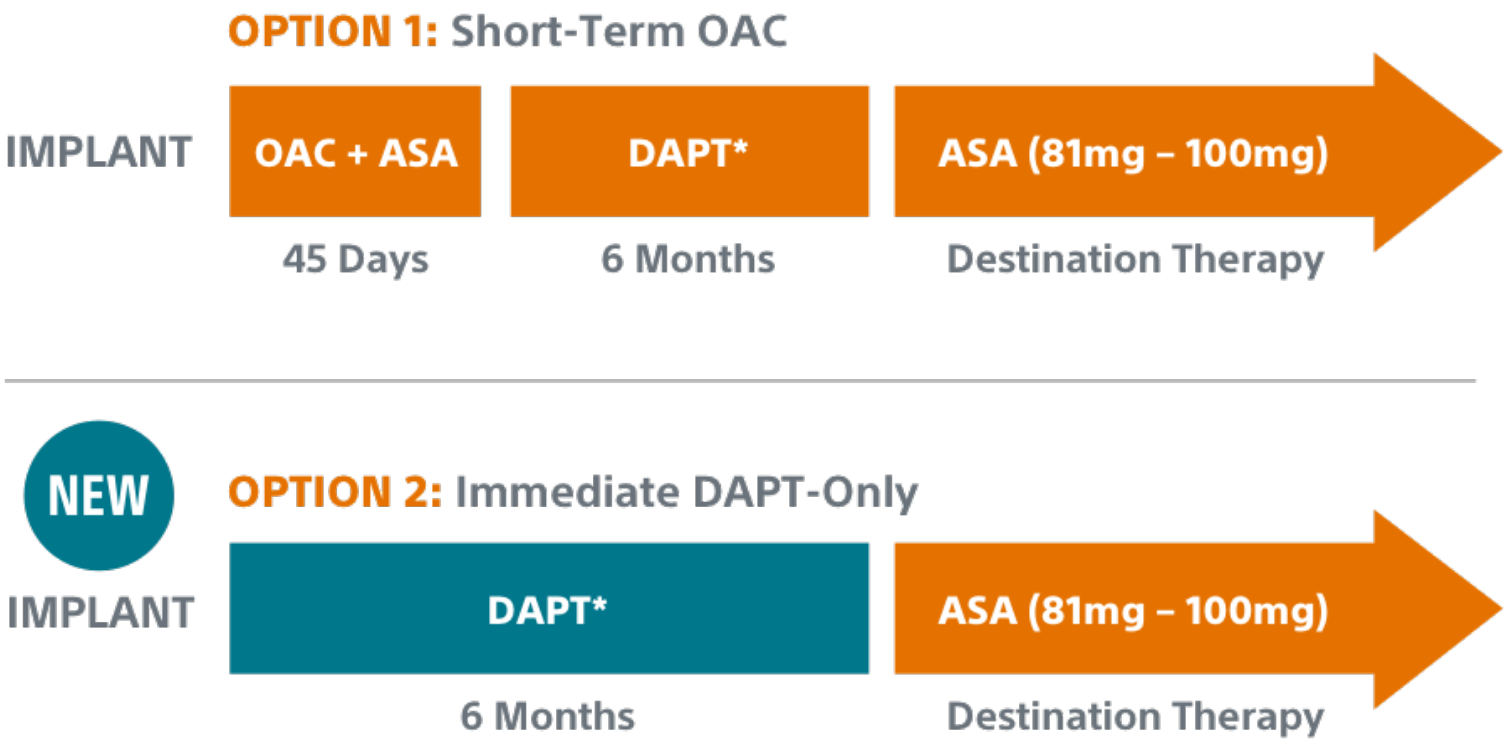
- Eligible patients must have a $CHADS_2$ score ≥ 2 or a **$CHA_2DS_2$-VASc score ≥ 3**
- Patients must be **suitable for short-term warfarin**, but deemed **unable to take long-term oral anticoagulation**
- **Documented evidence of a formal shared decision interaction between the patient and an independent 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

# Post-Implant Anticoagulation




*At TEE, if leak >5mm, patients remain on OAC + ASA until seal is documented (leak <5mm), skipping the P2Y12 inhibitor + ASA pharmacotherapy*

# 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Afib

| Recommendations for Percutaneous Approaches to Occlude the LAA Referenced studies that support the recommendations are summarized in the Online Data Supplement. | | |
|---|---|---|
| **COR** | **LOE** | **Recommendations** |
| **2a** | **B-NR** | 1. In patients with AF, a moderate to high risk of stroke ($CHA_2DS_2$-VASc score ≥2), and a contraindication (Table 14) to long-term oral anticoagulation due to a nonreversible cause, percutaneous LAAO (pLAAO) is reasonable.[1–4] |
| **2b** | **B-R** | 2. In patients with AF and a moderate to high risk of stroke and a high risk of major bleeding on oral anticoagulation, pLAAO may be a reasonable alternative to oral anticoagulation based on patient preference, with careful consideration of procedural risk and with the understanding that the evidence for oral anticoagulation is more extensive.[1–3,5,6] |