



***“Minimally invasive” therapies for  
the Structural Heart Problems***

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# AGENDA

- **Aortic valve stenosis**
  - What is it?
  - Symptoms ?
  - Therapies available ?
- **Atrial fibrillation**
  - What is Atrial Fibrillation?
  - The Connection Between A fib and Stroke Risk
  - Treatment Options

# AORTIC VALVE STENOSIS

# AORTIC VALVE STENOSIS

## MECHANISMS

- Mainly solid **calcium deposits** within the valve cusps
- Similar risk factors to Coronary Artery Disease (CAD)
- High coincidence of CAD and AS in same individual
- Typically manifests itself in the 6th, **7th, and 8th decades** of life

Healthy Aortic Valve



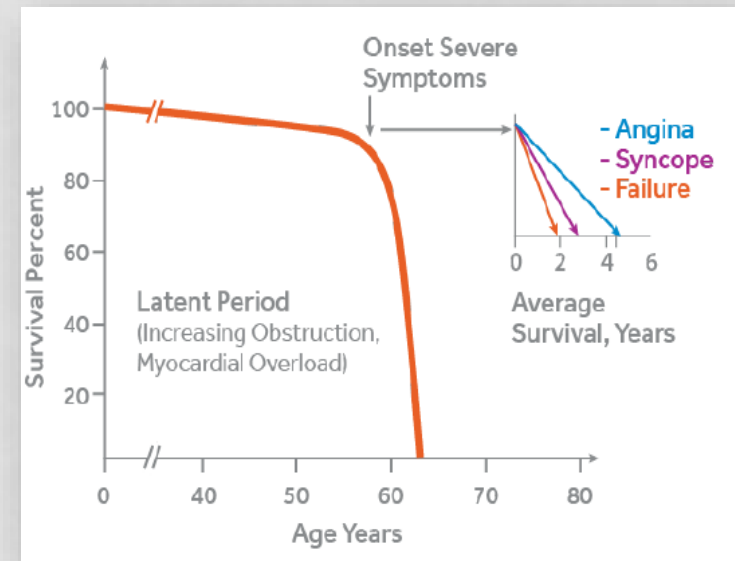
Stenotic Aortic Valve



# AORTIC VALVE STENOSIS (AS)

## PROGNOSIS IF UNTREATED

- Approximately **300,000** people in the U.S. are diagnosed annually with severe, symptomatic AS
- Onset of **shortness of breath** and other heart failure symptoms portends a **poor** prognosis
- Typical symptoms of AS:
  - I. Chest pain (Angina)
  - II. Fainting or near fainting
  - III. Shortness of breath (HF)
- After becoming symptomatic with signs of heart failure, the average patient **survival is two years** without treatment



# ACC/AHA GUIDELINES

## TREATMENT OF AORTIC STENOSIS

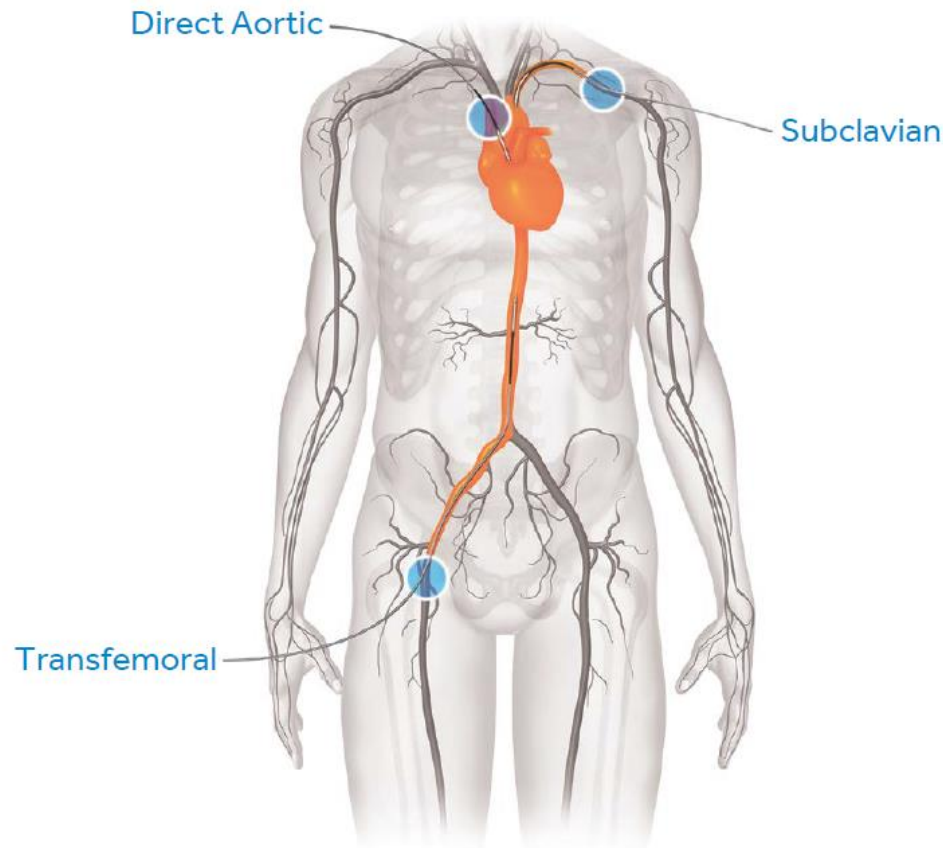
### According to the AHA/ACC guidelines:

“...otherwise healthy patients with severe VHD who become symptomatic should nearly always be considered for intervention.”

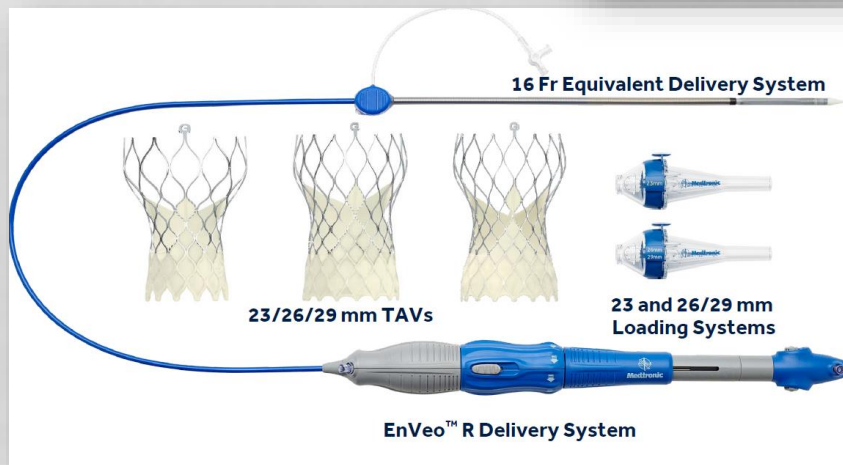
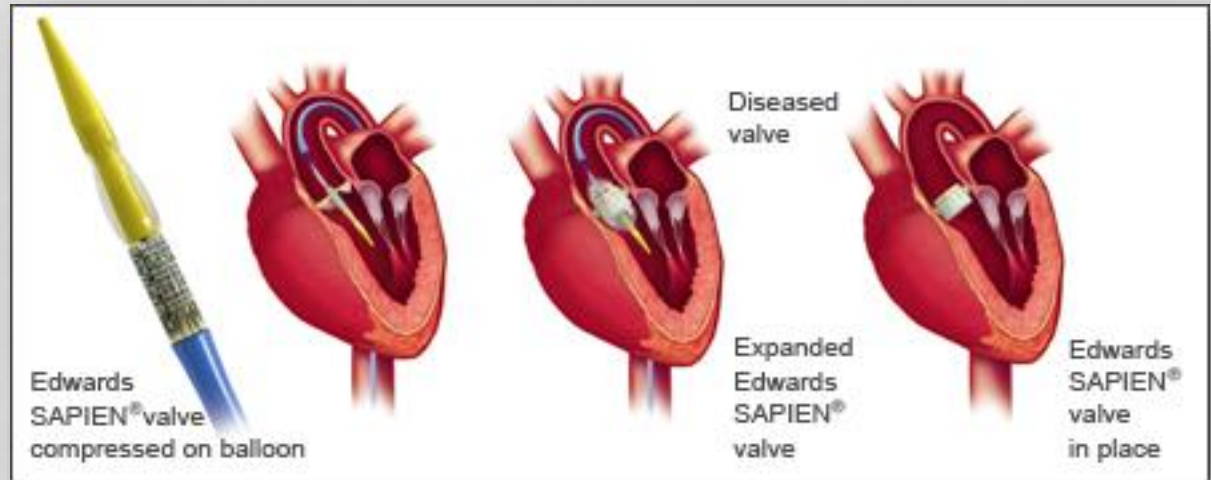
### Class I Recommendation:

Patients with severe VHD should be evaluated by a multidisciplinary Heart Valve Team when intervention is considered (LOE C).

# TRANSCUTANEOUS AORTIC VALVE REPLACEMENT - TAVR



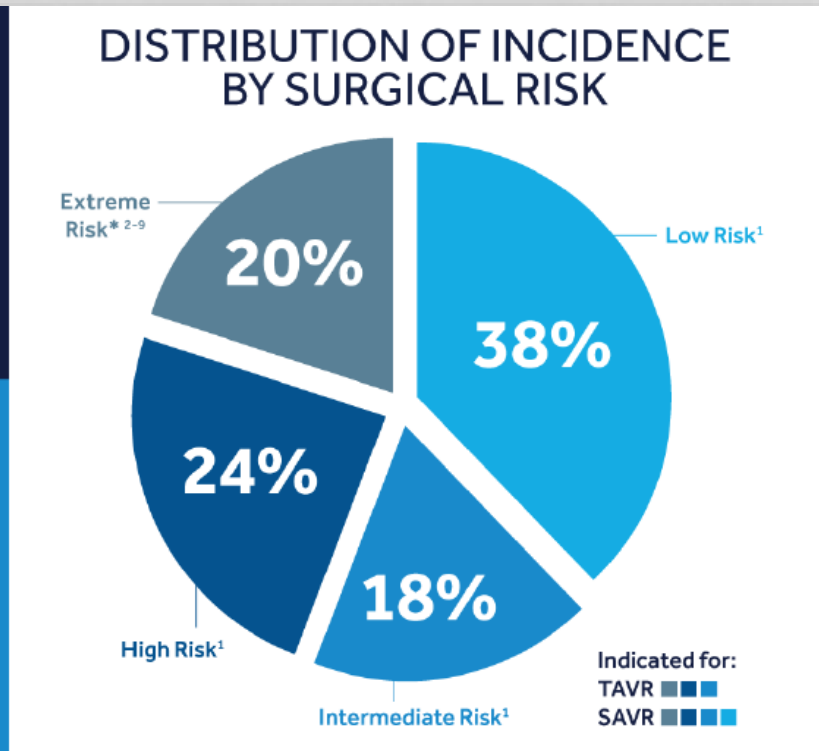
# COMMERCIALLY AVAILABLE "TAVR" PRODUCTS





# INCIDENCE OF SEVERE AORTIC STENOSIS IN UNITED STATES

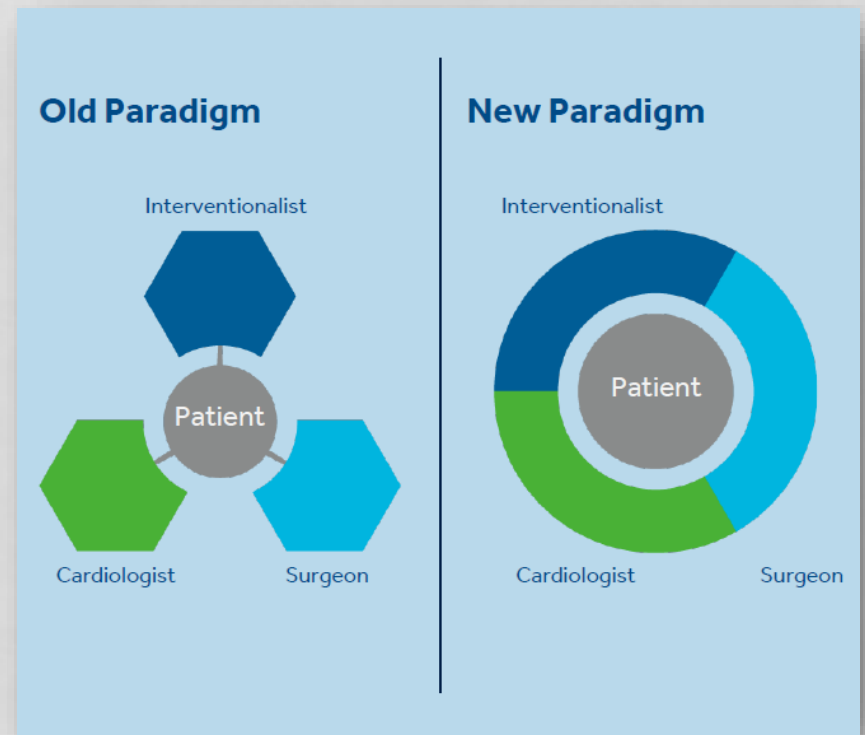
## STRATIFIED BY SURGICAL RISK



# MULTIDISCIPLINARY HEART VALVE TEAM

A patient may be best served by a multidisciplinary heart valve team that may include:

- Cardiologists
- Surgeons
- Structural valve interventionalists
- Cardiovascular imaging specialists
- Cardiovascular surgeons
- Anesthesiologists
- Nurses and Valve Coordinator



# PATIENT EVALUATION AT THE HEART VALVE CLINIC

## Example of Testing Conducted at a Heart Valve Clinic

- CT Scan
- Echo
- Labs
- EKG
- Physical Exam
- STS Score
- Assessment of Independent Living
- Gait Test/Grip Strength
- MMSE2
- NYHA Class
- Cardiac Catheterization

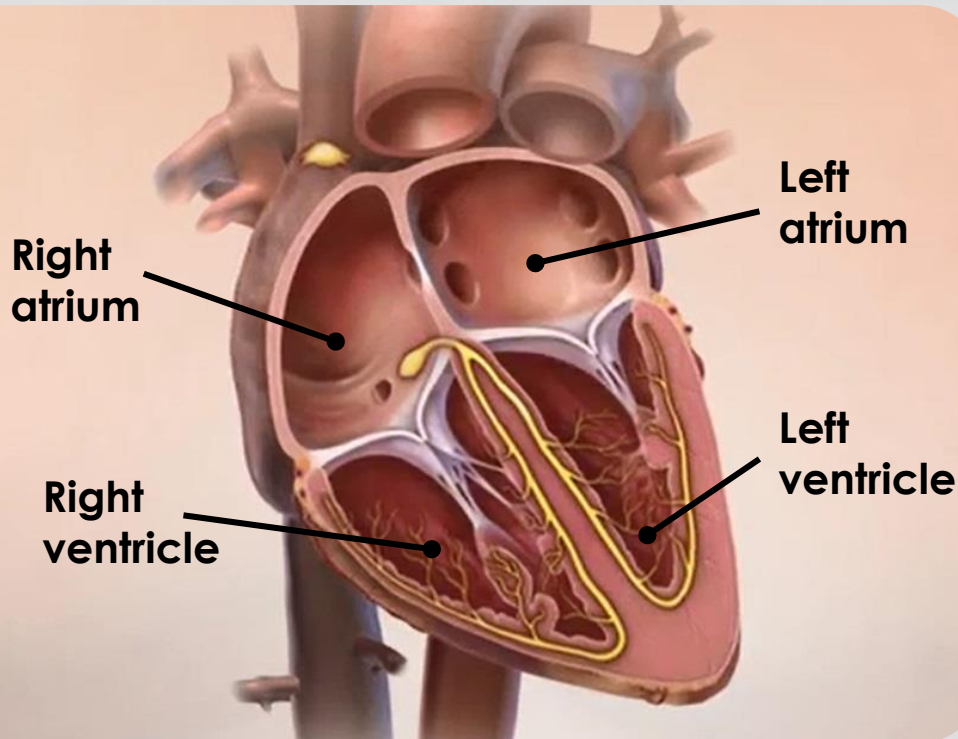


# ATRIAL FIBRILLATION OVERVIEW



# HOW THE HEART WORKS

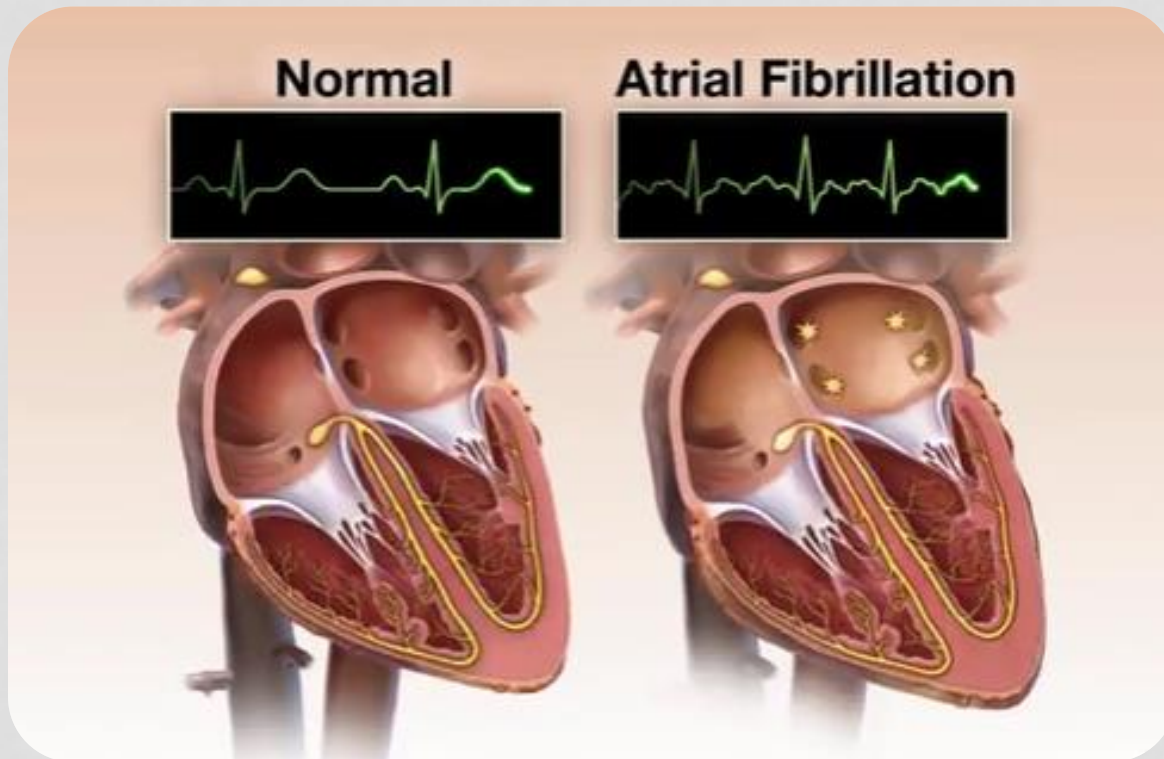
- The heart is divided into four chambers
  - **Atria:** two small, upper chambers
  - **Ventricles:** two larger, lower chambers



- Together, they pump blood to and from other parts of your body

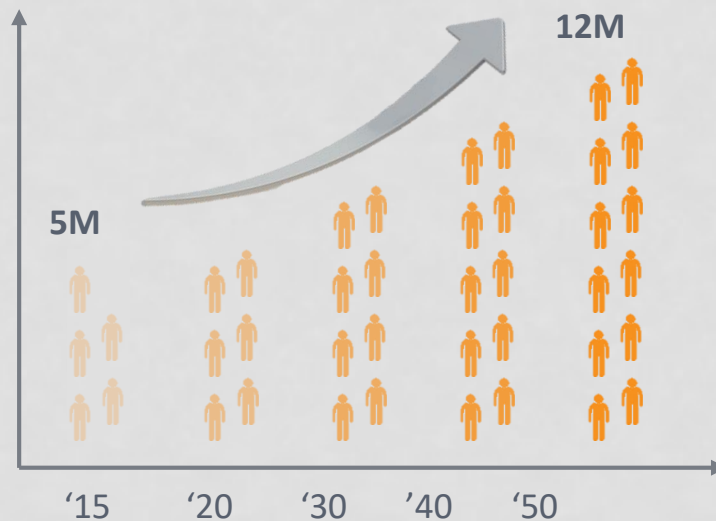
# WHAT IS ATRIAL FIBRILLATION

- Atrial Fibrillation or Afib is a heart condition that causes the upper chambers of your heart to beat too fast and in a chaotic rhythm



# YOU ARE NOT ALONE

- Atrial Fibrillation is a common cardiac arrhythmia and is a growing problem

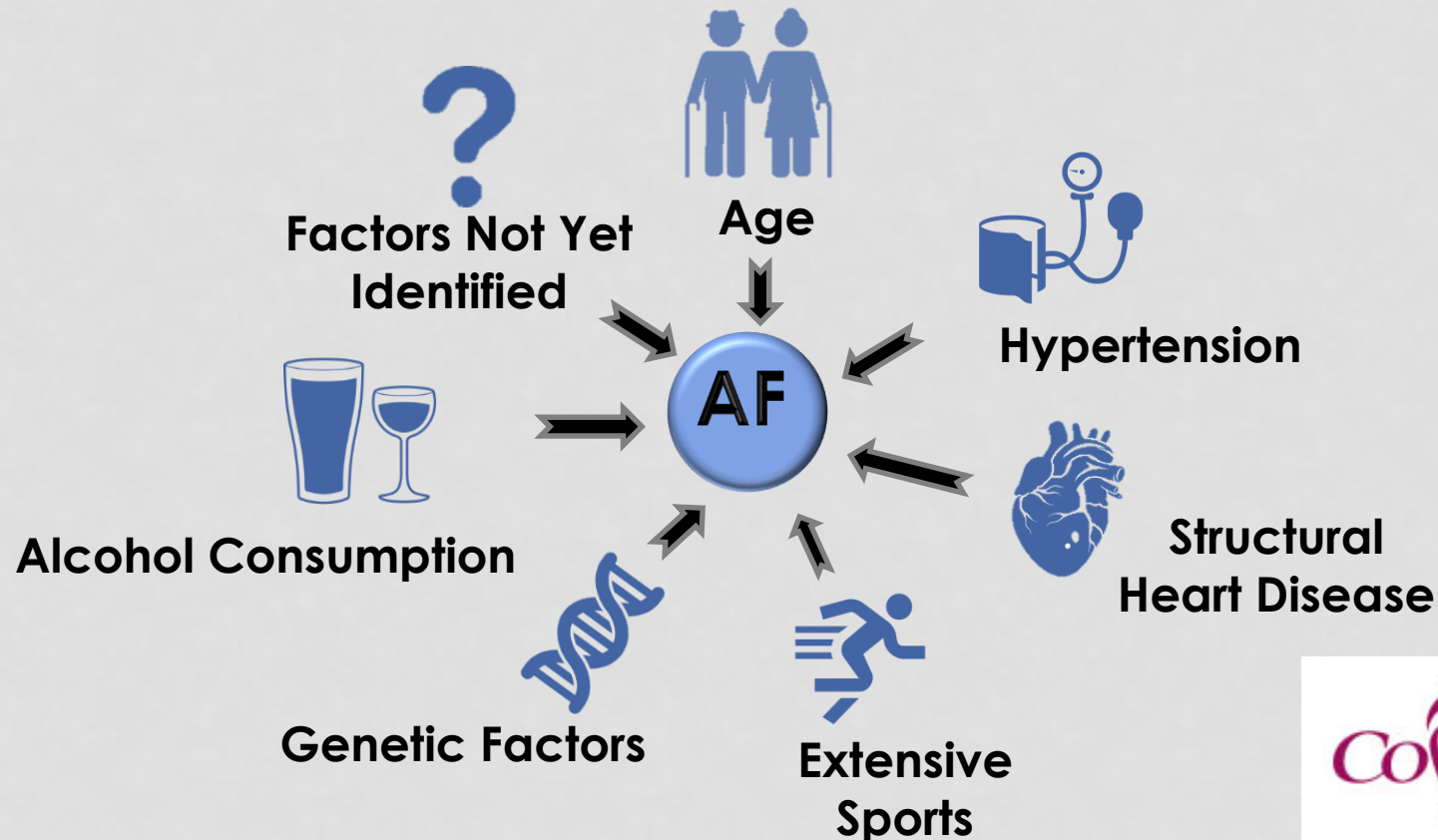


- ~5 M people with AF in U.S.<sup>1</sup>
- By 2050, up to 12 million Americans may be affected<sup>1</sup>

- Significant impact on your quality of life
- Treatment options are available

# WHAT CAUSES ATRIAL FIBRILLATION?

- As you grow older, the risk of Afib increases, especially after age 60





# SIGNS AND SYMPTOMS

Shortness of  
Breath



Racing Heart,  
Fluttering or  
Palpitations



YAWN!



Fatigue



Dizziness or  
Lightheadedness

# ATRIAL FIBRILLATION & STROKE RISK

# DID YOU KNOW?

- People with Afib may be at greater risk for stroke than people with normal heart rhythms<sup>2</sup>

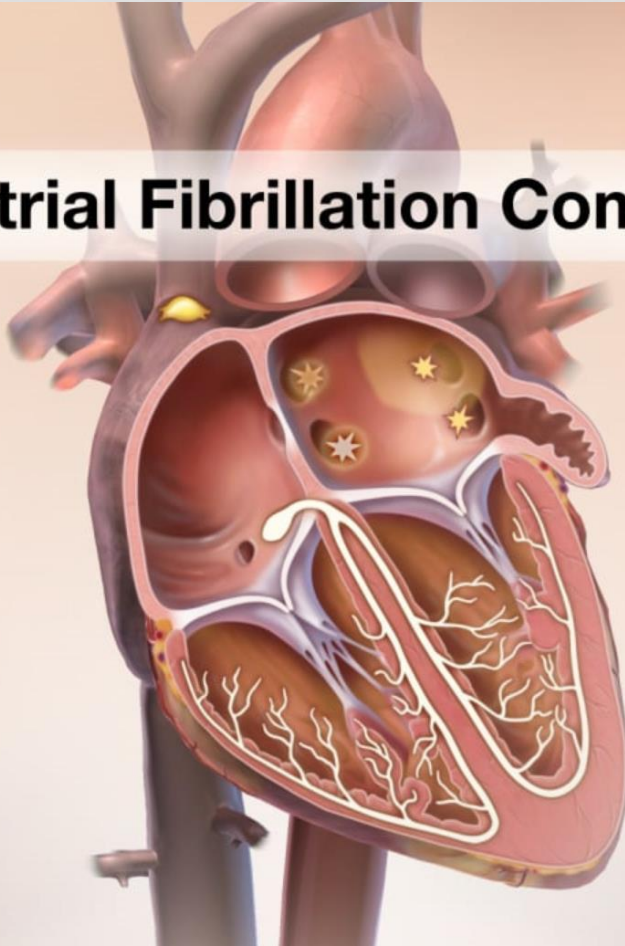


# WHY AFIB MATTERS

- AF can put you at risk for other complications
  - **Blood Clots:** The irregular heart rhythm can cause blood to pool and form clots in an area of your heart called the Left Atrial Appendage (LAA)
  - **Stroke:** If a blood clot forms in the LAA, it can escape and travel through to the brain and cause a stroke
  - **Heart Failure:** If atrial fibrillation continues over a long period of time, the decreased efficiency of the heart can lead to heart failure

# WHY AFIB MATTERS VIDEO

## Atrial Fibrillation Complications



Atrial Fibrillation  
increases risk of:

- Blood clots
- Stroke
- Heart failure

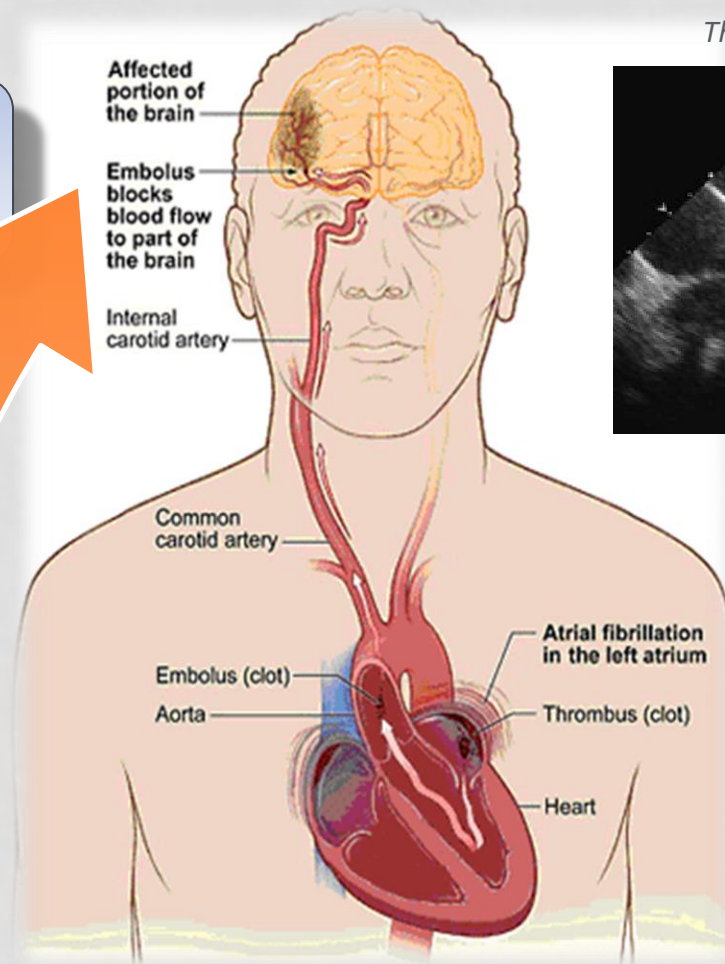
# BLOOD CLOTS & STROKE RISK

The clot lodges itself in the blood vessels of the brain, restricting blood flow and causing a stroke

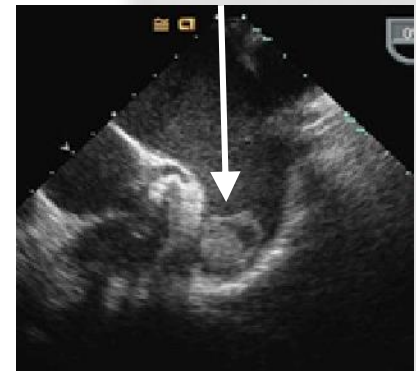
The blood clot dislodges from the LAA and travels through arterial system

The stagnant blood becomes an ideal environment for a blood clot to form

Fibrillation causes blood to stagnate in the left atrial appendage



*Thrombus in LAA*



# DID YOU KNOW?

- Approximately **1 in 3** people with atrial fibrillation will have a stroke in his or her lifetime<sup>3</sup>
- More than **90%** of stroke-causing clots that come from the heart originate in the LAA
- Afib-related strokes are more frequently fatal and disabling<sup>4,5</sup>

# SYMPTOMS OF A STROKE

- Learn the warning signs and act FAST

# BEFAST

**BALANCE**



Loss of  
balance,  
headache or  
dizziness

**EYES**



Blurred vision

**FACE**



One side of  
the face is  
drooping

**ARMS**



Arm or leg  
weakness

**SPEECH**



Difficulty with  
speech

**TIME**

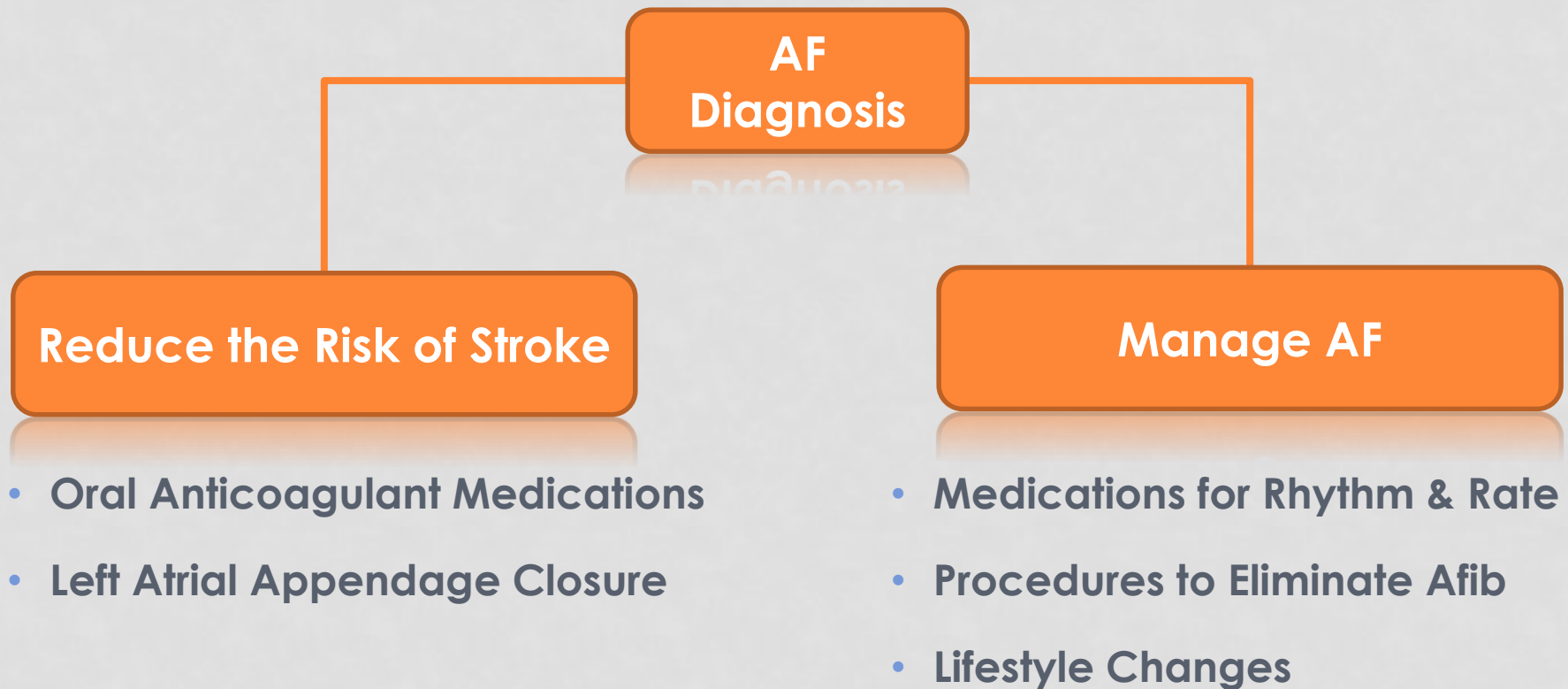


Time to call for  
ambulance  
immediately



# TREATMENT OPTIONS

# GOALS OF TREATMENT



# HOW IS AFIB MANAGED?



## Rate Control

- Treatment to make sure the heart doesn't beat too quickly during Afib



## Rhythm Control

- Treatment to restore the heart's rhythm to a normal state and keep it there



## Lifestyle Changes

- Get regular exercise, eat a heart-healthy diet, don't smoke, watch alcohol and caffeine intake

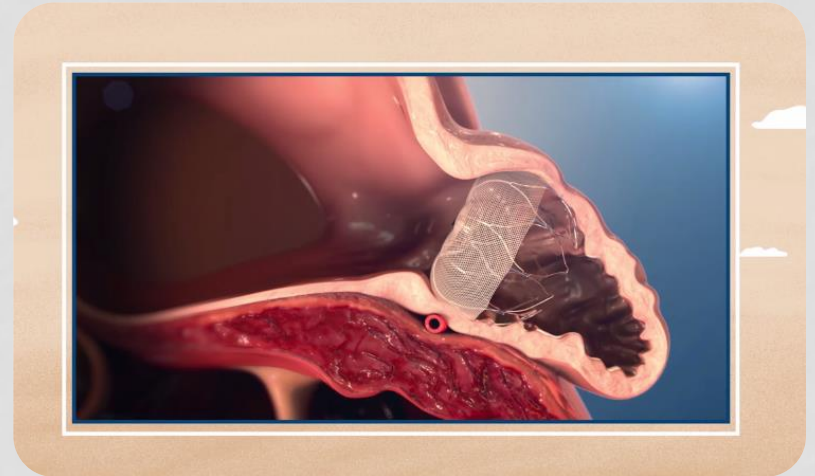


## Atrial Fibrillation Procedures

- Cardioversion or Ablation procedures to restore rhythm

# REDUCING THE RISK OF AFIB-RELATED STROKE

- Treatment options are available to protect you from stroke or related complications from blood clots
- **Oral Anticoagulation Medicine (Blood Thinners)**
- **Left Atrial Appendage Closure (LAAC)**



# ORAL ANTICOAGULANT MEDICATIONS (BLOOD THINNERS)

- Medications can reduce the risk of blood clots that could lead to stroke
  - **Anti-platelet medicines**, including aspirin, keep platelets in the blood from sticking together and forming clots
  - **Anti-clotting medicines**, such as warfarin (Coumadin®), also help prevent clots from forming in your blood

# ORAL ANTICOAGULANT MEDICATIONS (BLOOD THINNERS)

- **Common blood thinners include**
  - warfarin (Coumadin®)
  - Eliquis®
  - Pradaxa®
  - Xarelto®
  - Savaysa®
- Most people can take blood thinners for years without serious side effects
- But because blood thinners help prevent clots by thinning the blood, they also increase the risk of bleeding<sup>2</sup>

# TALK TO YOUR DOCTOR

- When considering your treatment options, your cardiologist will weigh your risk of a stroke against your risk of a serious bleeding problem

**Risk of a  
stroke**



**Risk of a  
serious bleed**

# LEFT ATRIAL APPENDAGE CLOSURE

- Closing the LAA is an effective way to reduce stroke risk in people with Afib not caused by heart valve problems
- WATCHMAN is a permanent implant designed to close off the LAA so blood clots cant form there and escape to cause a stroke



# WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE IMPLANT

- WATCHMAN is a one-time procedure that may reduce stroke risk for a lifetime
- It is as effective at reducing the risk of stroke as warfarin (Coumadin®)
- Unlike warfarin, the WATCHMAN Implant also reduces the long-term risk of bleeding
- WATCHMAN is about the size of a quarter and made from very light and compact materials commonly used in many other medical implants

# IN A CLINICAL STUDY

In a clinical trial,

**9 OUT OF 10 PEOPLE**  
**WERE ABLE TO STOP TAKING WARFARIN**  
just 45 days after getting WATCHMAN<sup>6</sup>



# WATCHMAN PROCEDURE



- The WATCHMAN Implant doesn't require open heart surgery. It cannot be seen outside the body

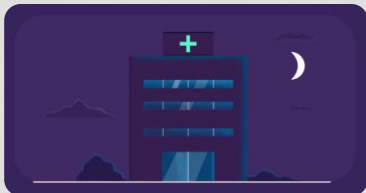


- The procedure is typically done under general anesthesia



- Typically takes less than an hour

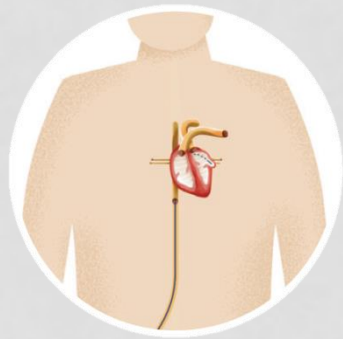
People commonly stay in the hospital overnight and leave the next day



# WATCHMAN PROCEDURE



**1.** To implant WATCHMAN, your doctor makes a small cut in your upper leg and inserts a narrow tube.



**2.** Your doctor then guides WATCHMAN through the tube, into your LAA.

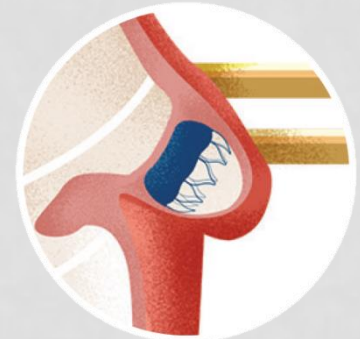


**3.** The procedure is done under general anesthesia and typically takes About an hour.

People who get the WATCHMAN Implant usually stay in the Hospital overnight and go home the next day.



**4.** After the procedure, you'll take warfarin until your LAA is permanently closed off – usually just 45 days.

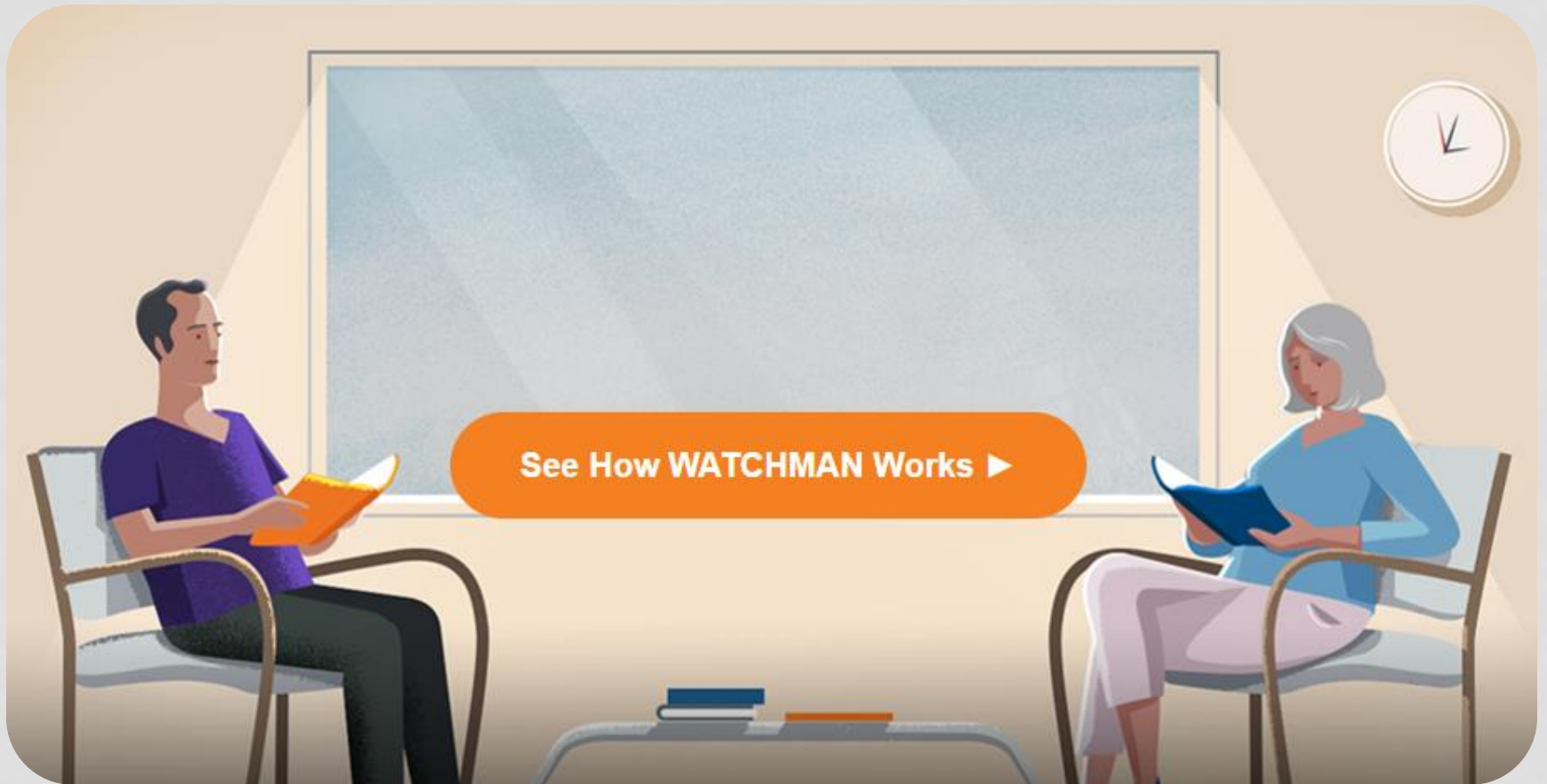


**5.** During that time, heart tissue grows over the WATCHMAN Implant to form a barrier against blood clots.

# WATCHMAN PROCEDURE

- As with any medical procedure, there are risks involved with WATCHMAN
- See the Important Safety Information for a list of possible complications, and talk to your doctor so you thoroughly understand all the benefits and risks of the WATCHMAN Implant

# SEE HOW WATCHMAN WORKS



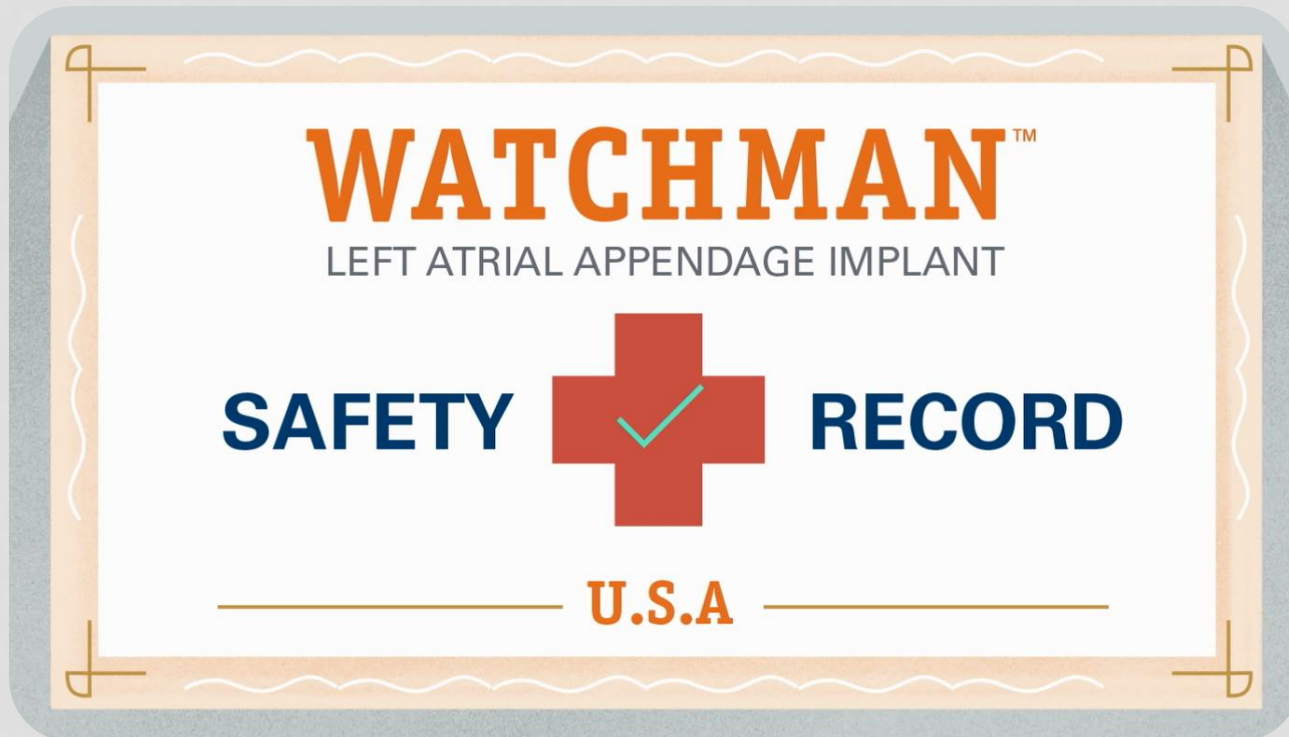
# WATCHMAN HAS BEEN STUDIED FOR MORE THAN 10 YEARS

- The WATCHMAN Implant is the **only FDA-approved implant** proven to safely and effectively lower stroke risk in patients with AFib not caused by heart valve problems



# WATCHMAN HAS A PROVEN SAFETY RECORD

Worldwide, **more than 30,000 people** have received the WATCHMAN Implant<sup>7</sup>





# WHO IS WATCHMAN FOR?

- WATCHMAN may be right for you if:
  - ✓ You have Atrial Fibrillation not caused by heart valve problem

**And**

- ✓ You've experienced major bleeding while taking blood thinners

**Or**

- ✓ You have a lifestyle, job or health condition that puts you at risk for major bleeding

# PEOPLE WHO SHOULD NOT BE CONSIDERED FOR WATCHMAN

- People who SHOULD NOT receive the WATCHMAN Implant include but are not limited to those who:
  - ✓ Cannot take warfarin (Coumadin®), aspirin or clopidagrel (Plavix®)
  - ✓ Should not or cannot undergo heart catheterization procedures
  - ✓ Have an allergy or sensitivity to nitinol (nickel and titanium)
  - ✓ Have a left atrial appendage that does not fit the WATCHMAN Implant
  - ✓ Are taking blood thinners for a condition other than atrial fibrillation

# COSTS AND COVERAGE

- WATCHMAN is covered for eligible Medicare patients who meet certain national coverage criteria
- It is also covered by an increasing number of commercial insurers

# HELPFUL RESOURCES

- LAAC Clinical Coordinator  
Deb Best, (989) 583-7171  
Dr. Firas Alani (989) 583-4700
- WATCHMAN Left Atrial Appendage Closure Implant  
[www.WATCHMAN.com](http://www.WATCHMAN.com)
- Connect With WATCHMAN through Nurse's Line  
1-855-893-2606

# IMPORTANT SAFETY INFORMATION

- The WATCHMAN Device is a permanent implant designed to close the left atrial appendage in the heart in an effort to reduce the risk of stroke.

With all medical procedures there are risks associated with the implant procedure and the use of the device. The risks include but are not limited to accidental heart puncture, air embolism, allergic reaction, anemia, anesthesia risks, arrhythmias, AV (Arteriovenous) fistula, bleeding or throat pain from the TEE (Trans Esophageal Echo) probe, blood clot or air bubbles in the lungs or other organs, bruising at the catheter insertion site, clot formation on the WATCHMAN™ Closure Device, cranial bleed, excessive bleeding, gastrointestinal bleeding, groin puncture bleed, hypotension, infection/pneumonia, pneumothorax, pulmonary edema, pulmonary vein obstruction, renal failure, stroke, thrombosis and transient ischemic attack. In rare cases death can occur.

Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of the WATCHMAN Device.

# REFERENCES

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3. Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. ***Ann Thorac Surg***. 1996;61:755-759.
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6. Holmes DR Jr, Kar S, Price MJ, et al. Prospective randomized evaluation of the Watchman Left Atrial Appendage Closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL trial. ***J Am Coll Cardiol***. 2014;64(1):1-12.
7. Holmes DR Jr, Doshi SK, Kar S, et al. Left atrial appendage closure as an alternative to warfarin for stroke prevention in atrial fibrillation: a patient-level meta-analysis. ***J Am Coll Cardiol***. 2015;65(24):2614-2623.
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