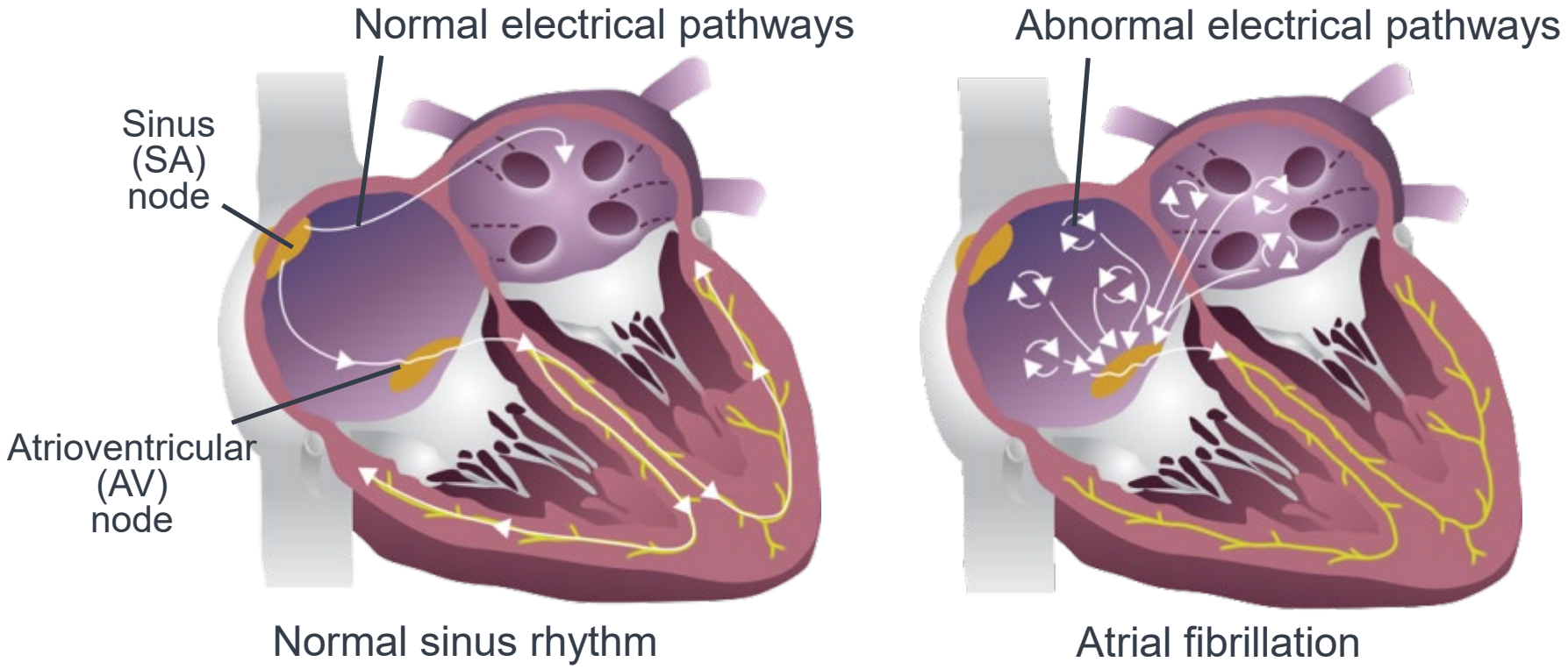
ROPER ST. FRANCIS HEALTHCARE

Options for Atrial Fibrillation Management

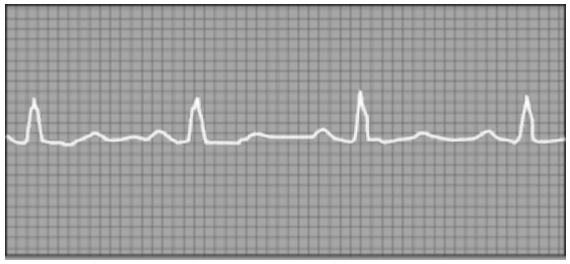
ABLATION AND LEFT ATRIAL APPENDAGE CLOSURE

Brett Baker MD FACC
Director Roper St. Francis Electrophysiology Laboratory

Atrial Fibrillation

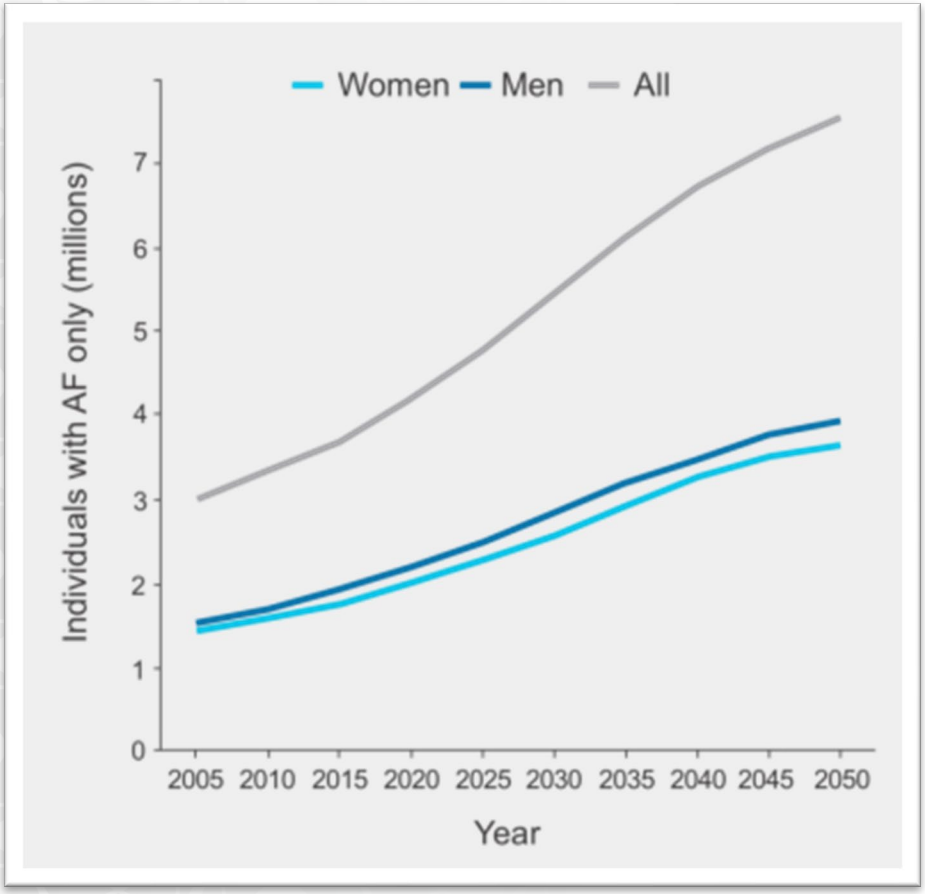


Normal sinus rhythm



Atrial fibrillation

AF Prevalence Is Large and Growing



- US AF Prevalence is estimated at > 3.5[1] million people and is predicted to double by 2035[1]
- Age-adjusted AF incidence is predicted to grow as a result of increased risk factors: obesity, hypertension, diabetes, and cardiovascular disease[2]

[1] Lloyd-Jones DM, Wang TJ, Leip EP, et al. Lifetime risk for development of atrial fibrillation: the Framingham Heart Study. *Circulation*. 2004;110(9):1042-1046.
[2] Miyasaka Y, Barnes ME, Gersh BJ, et al. Secular trends in incidence of atrial fibrillation in Olmsted County, Minnesota, 1980 to 2000, and implications on the projections for future prevalence. *Circulation*. 2006;114(2):119-125.

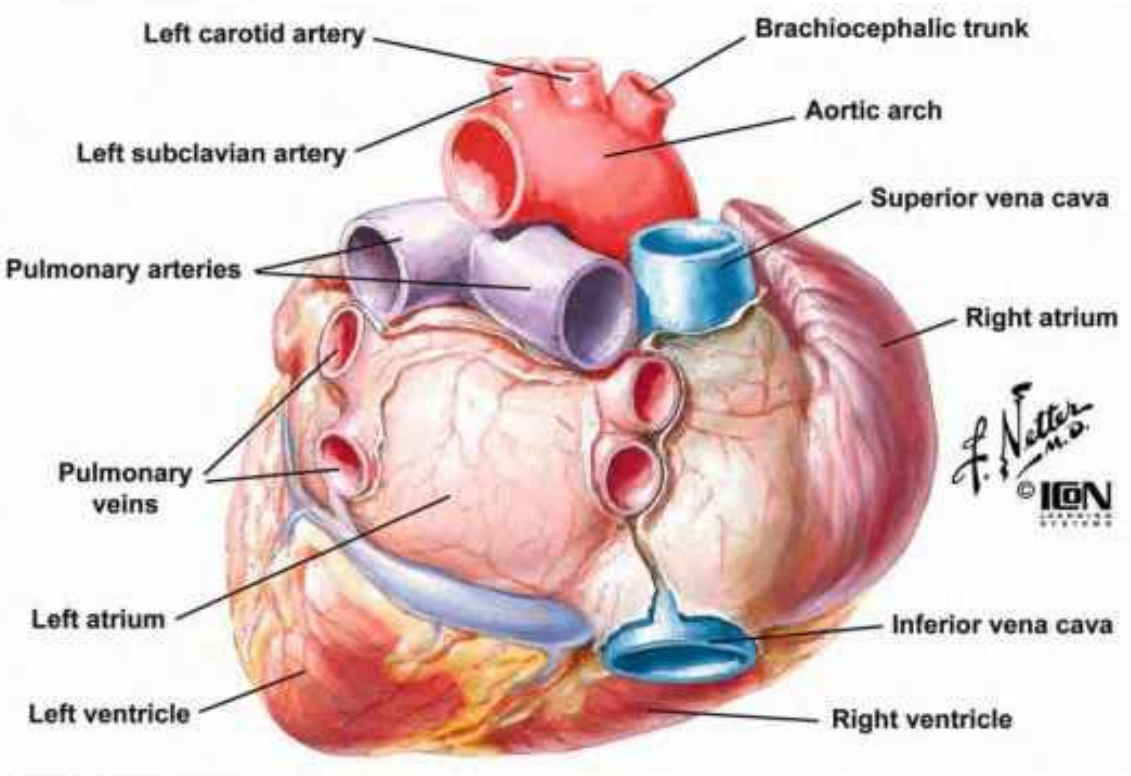
ROPER ST. FRANCIS

Atrial Fibrillation: Health Risks and Costs

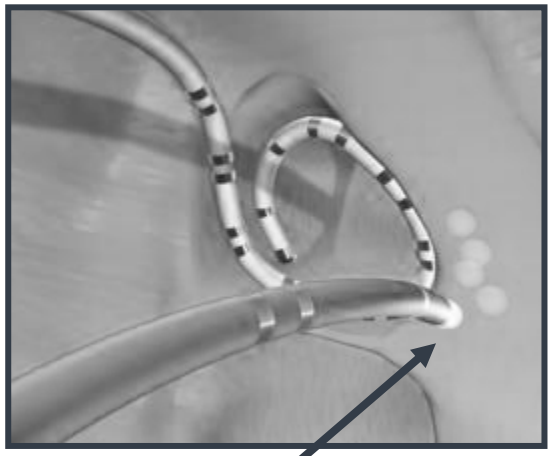
- Negative impact on quality of life[1,2]
- Leading cause of stroke: 5x increased risk[3]
- Increases risk of heart failure[4] and dementia
- Increases US healthcare system costs: $12 billion estimated cost to treat AF[5]

[1] Singh SN, et al. *J Am Coll Cardiol.* 2006;48:721-730.
[2] Kang Y. *Heart Lung.* 2006;35:170-177.
[3] Wolf PA, et al. *Stroke.* 1991;22:983-988.
[4] White PD: Heart disease. New York, NY, The McMillan Co, 1937.
[5] Kim MH, et al. *Adv.Ther.* 2009;26:847-857.

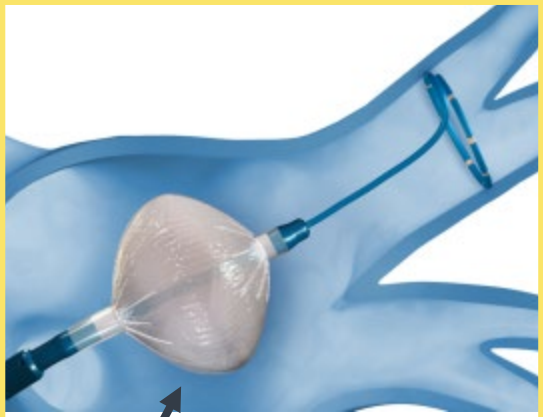
Pulmonary Vein Isolation



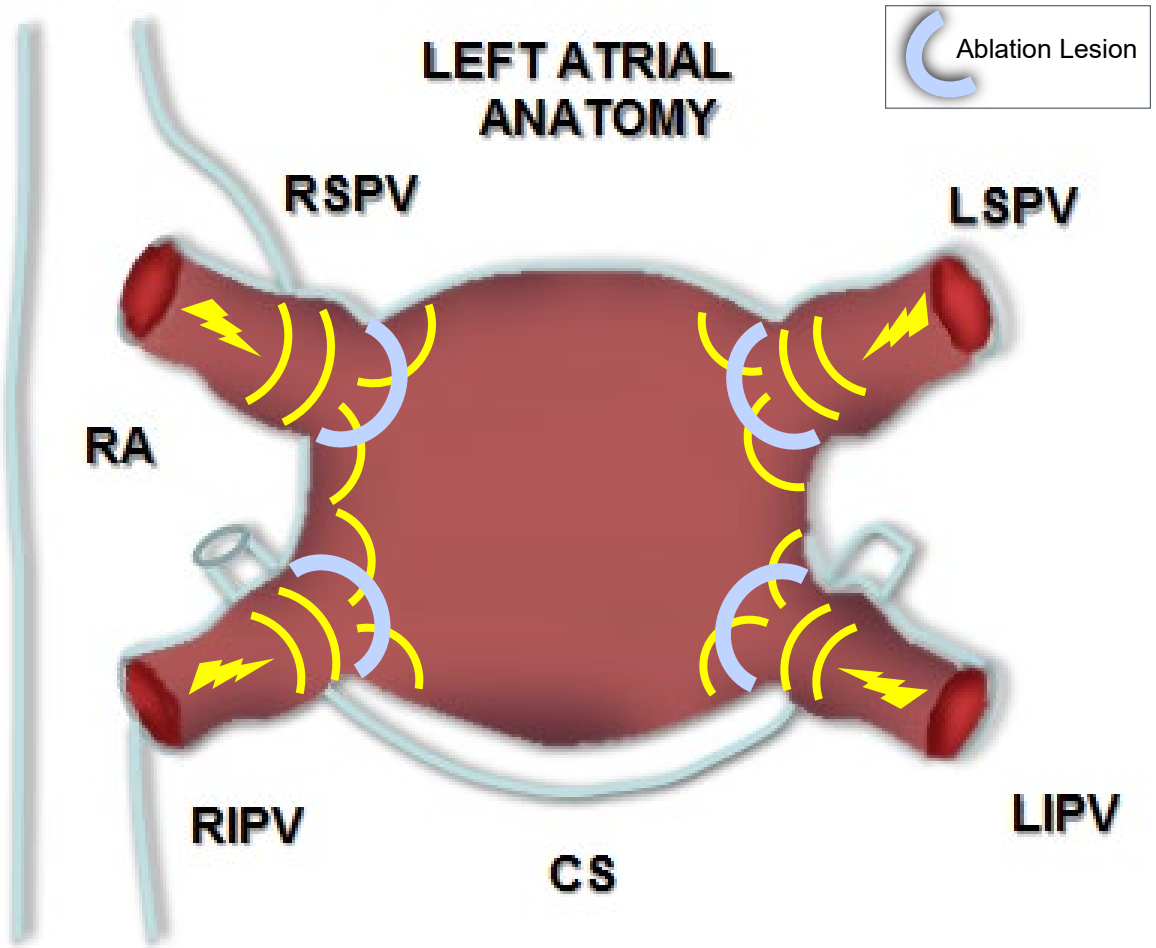
Ablation for Atrial Fibrillation: Pulmonary Vein Isolation



RF Ablation Catheter

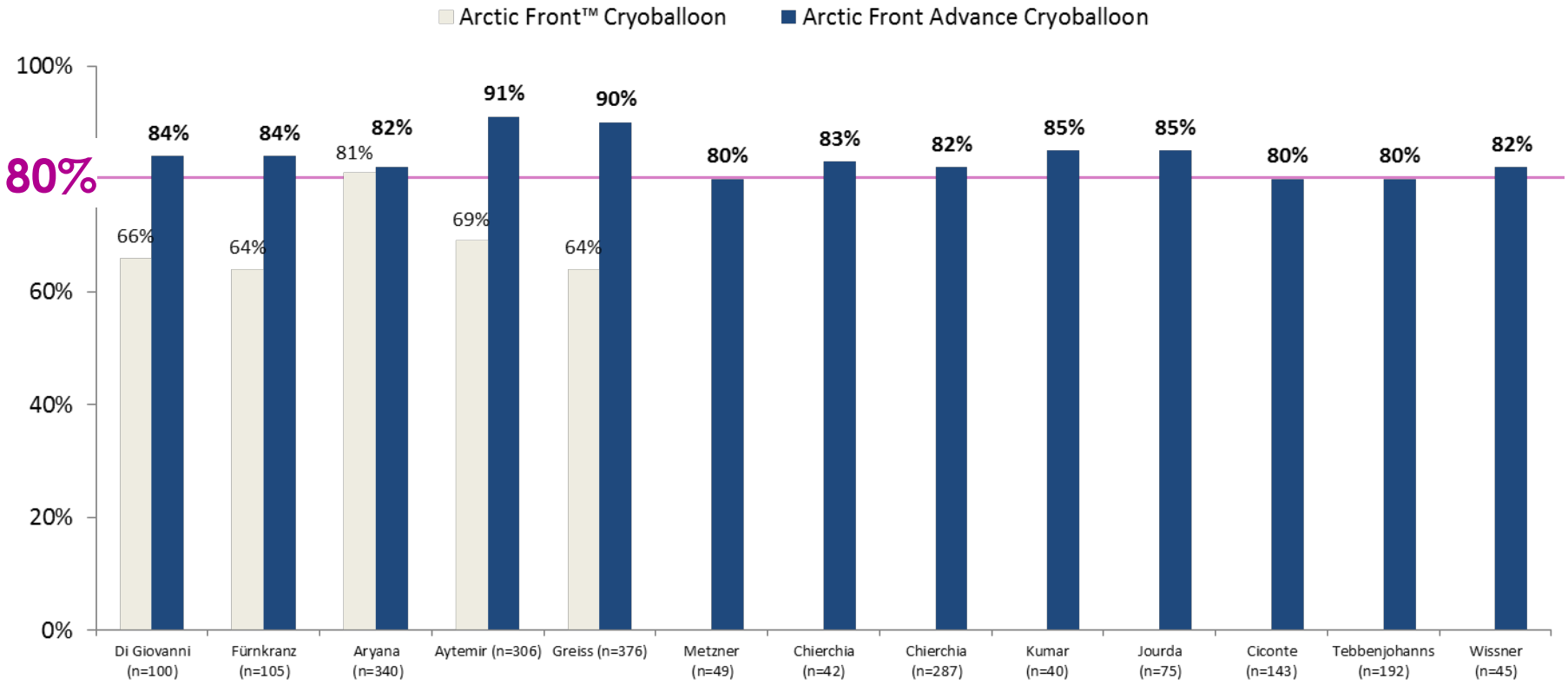


Cryoballoon Ablation Catheter



Single Procedure Freedom from Atrial Arrhythmia

ARCTIC FRONT ADVANCE™ CRYOBALLOON SINGLE CENTER PUBLISHED STUDIES



Arrhythmia monitoring methods and definition of procedure success (Freedom from AF Only or AF/AT/AFL) varied between studies.

Di Giovanni, et al. *J Cardiovasc Electrophysiol.* 2014; 25(8):834-9; Fürnkranz, et al. *Journal of Cardiovascular Electrophysiology.* 2014 ;25(8):840-4; Aryana, et al. *J Interv Card Electrophysiol*. 2014;41(2):177-186; Aytemir, et al. *Europace*. 2015;17(3):379-87; Greiss, et al. *PACE*. 2015 Jul;38(7):815-24; Metzner, et al. *Circ Arrhythm Electrophysiol.* 2014; 7(2):288-292; Chierchia, et al. *Europace.* 2014; Chierchia, et al. *J Cardiovasc Electrophysiol*. 2015; In Press; 16(5):639-644; Kumar et al. *J Interv Card Electrophysiol.* 2014;41(1):91-7; Jourda, et al. *Europace.* 2015;17(2):225-31; Ciconte, et al. *Heart Rhythm*. 2015;12(4):673-80; Tebbenjohanns, et al. *Europace.* 2015; Wissner, et al. *Europace.* 2015 Aug;17(8):1236-40

Factors Related to Treatment Success

1. Left Atrial Size
2. Age
3. BMI
4. Structural Heart Disease
5. Sleep Apnea
6. ETOH

CONVERGENT

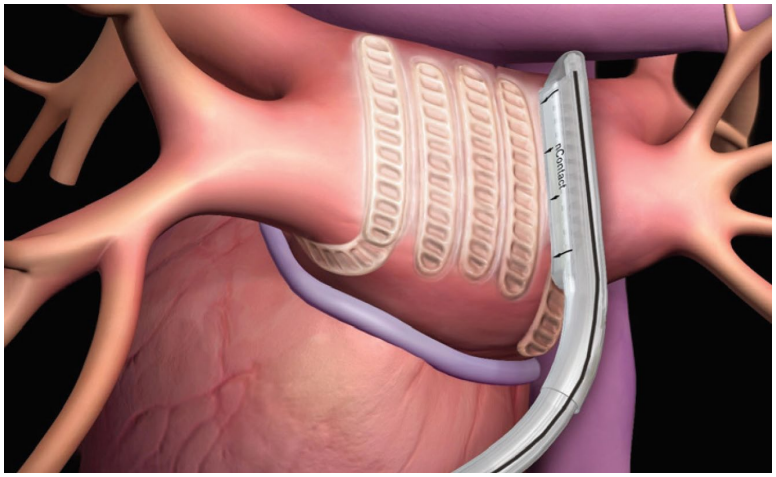
•The Convergent approach is a minimally invasive, comprehensive cardiac ablation that combines the expertise of cardiothoracic surgery AND electrophysiology

Who is the Ideal Candidate?

- Those who have symptomatic persistent or long-standing atrial fibrillation
- Those who have failed previous catheter treatments
- Those who have been ineffectively managed with antiarrhythmic drugs or cardioversion

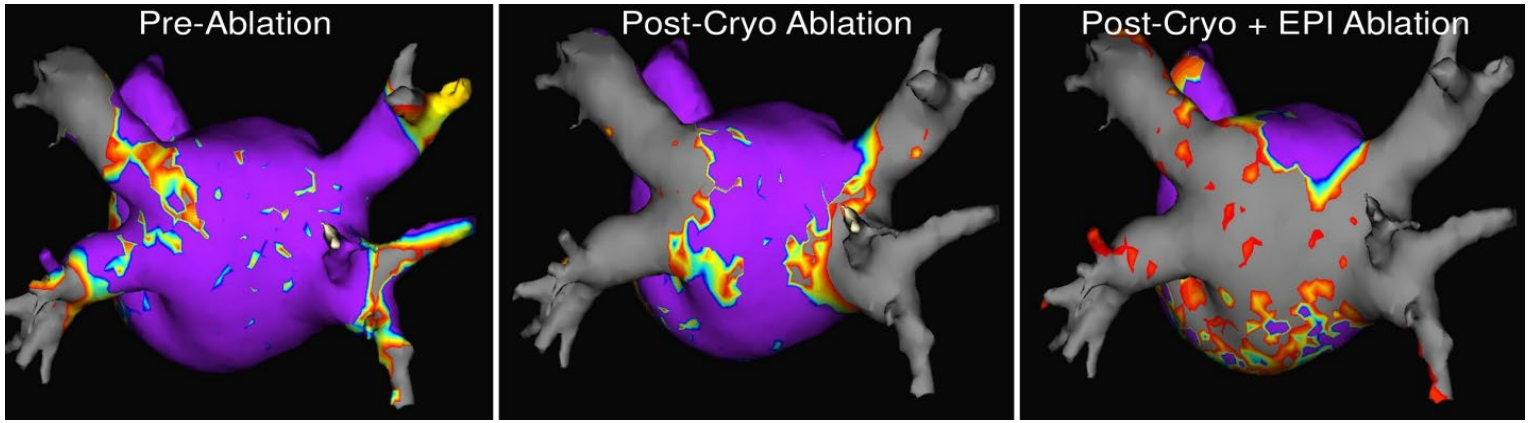
Who is NOT an Ideal Candidate?

- Anyone who has had a previous open heart surgery such as heart bypass or valve surgery



ROPER ST. FRANCIS

CONVERGENT



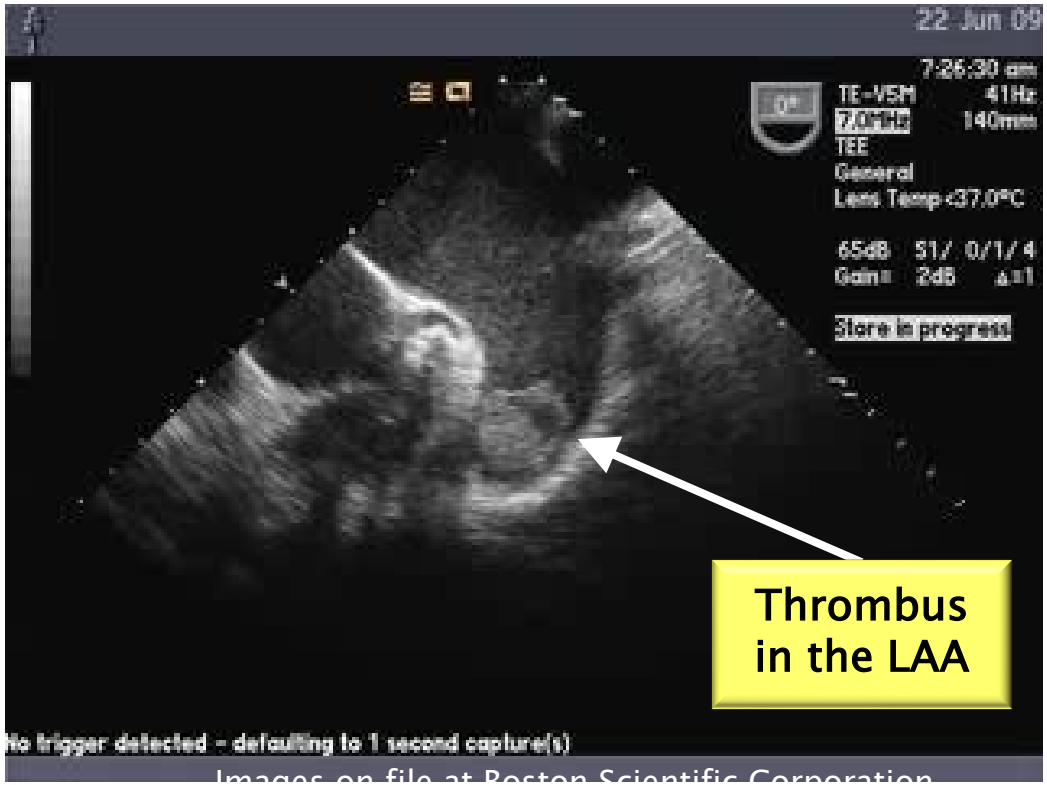
1 Makati, K. J., MD, Sherman, A., MD, Hogue, D., MS. Cryoballoon Ablation as the Endocardial Component in the Convergent Procedure: Single Center Outcomes: HRS 2015

2 Borut Gersak, MD, PhD, and Matevz Jan, MD. Long-Term Success for the Convergent Atrial Fibrillation Procedure: 4-Year Outcomes. Ann Thorac Surg 2016 by The Society of Thoracic Surgeons

91% of stroke in AF is caused by blood clots that form in the left atrial appendage (LAA)[1]

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

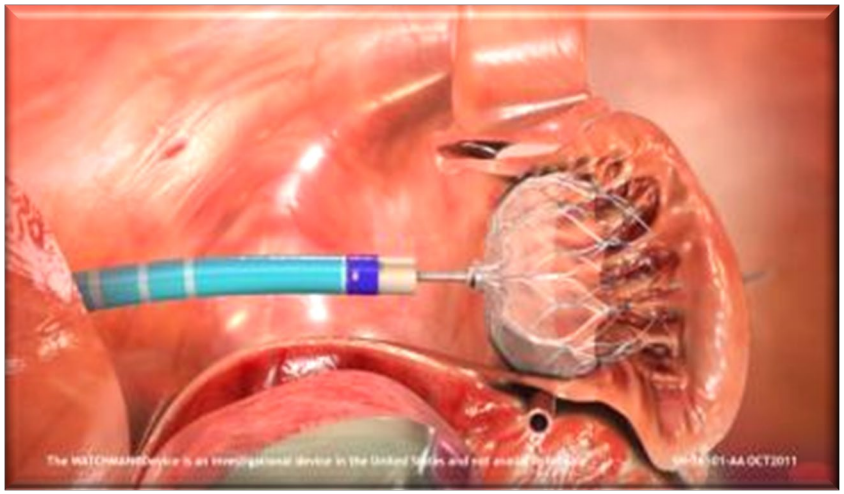
The blood clot, or portion of it, dislodges from the LAA and travels through arterial system

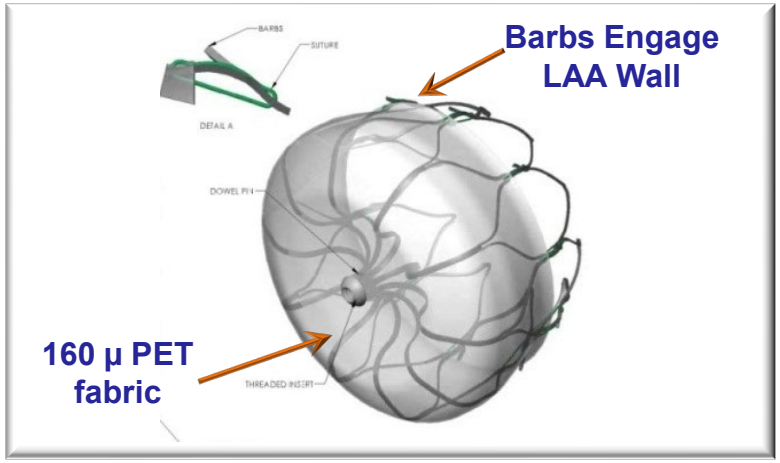


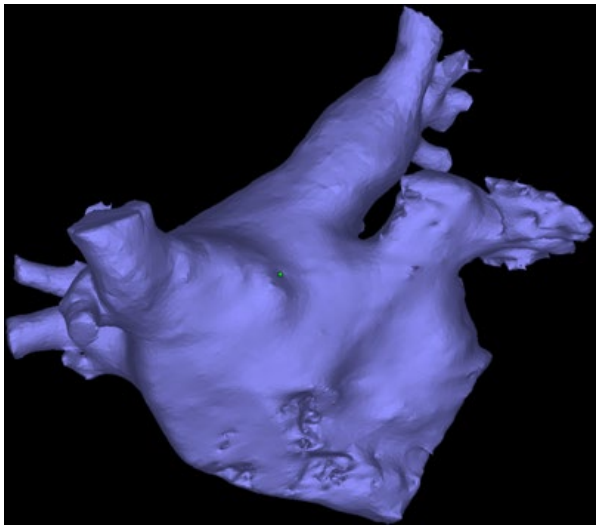
1 Blackshear JL. Odell JA., *Annals of Thoracic Surgery.* 1996;61:755-759

Stroke Prophylaxis in AF

- Difficulties with Anticoagulant use
  - Frequent Monitoring
  - Difficulty in Compliance (TTR 48-63%)
  - Drug / Diet Interactions
  - Bleeding Risk (ICH)
  - Risks in Elderly (Falls, Poly-pharmacy)
- Autopsy & TEE data implicate LAA
- LAA Closure Devices

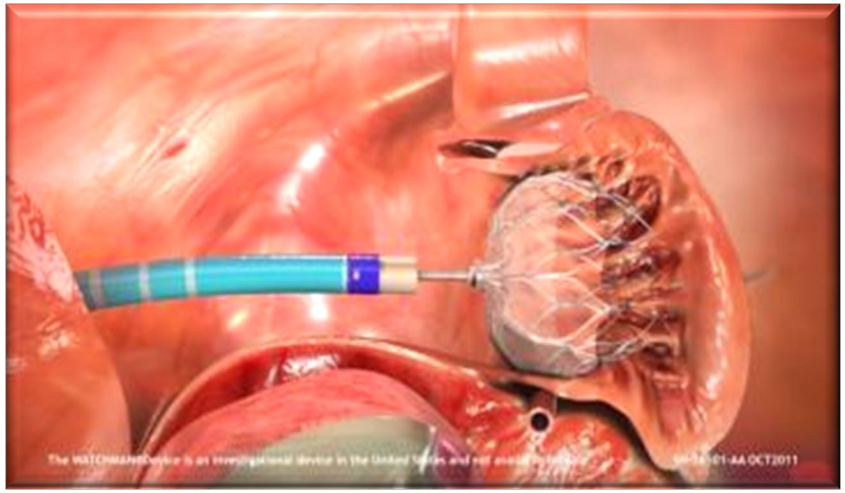


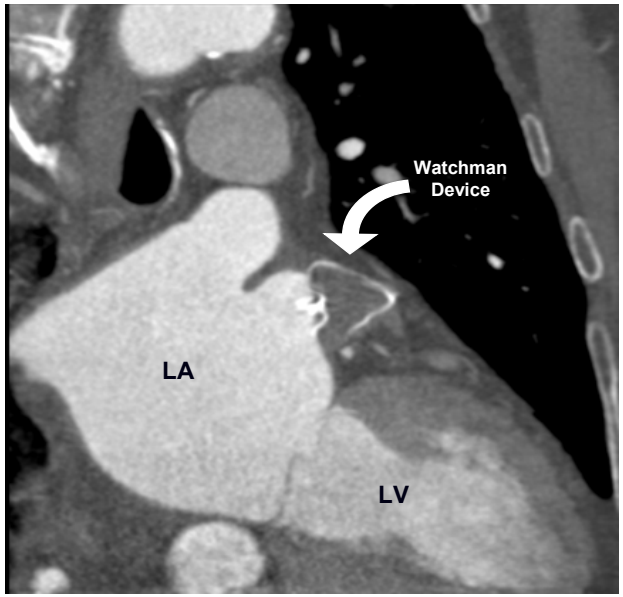




ROPER ST. FRANCIS

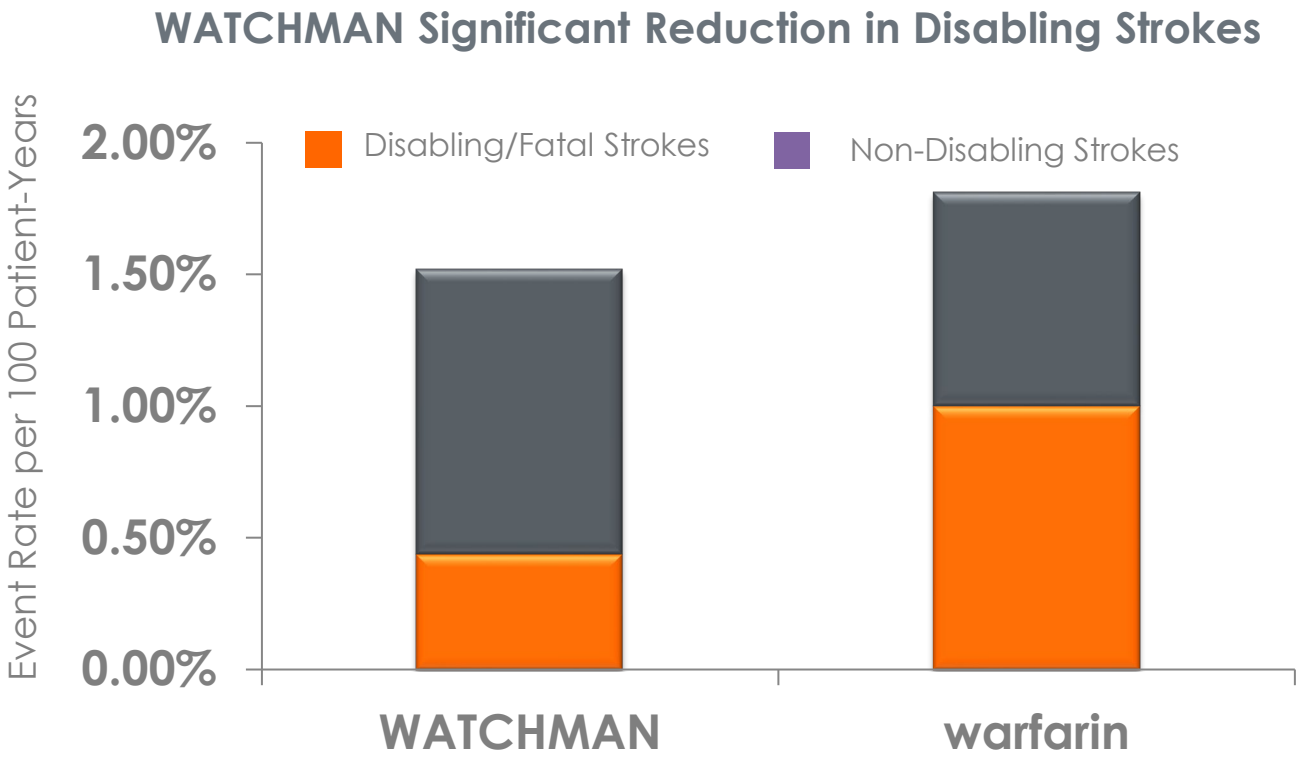
Stroke Prophylaxis in AF





WATCHMAN is Proven to Reduce Disabling Strokes

At 5 years, WATCHMAN patients had a 55% lower relative risk of disabling or fatal strokes compared to patients treated with warfarin.



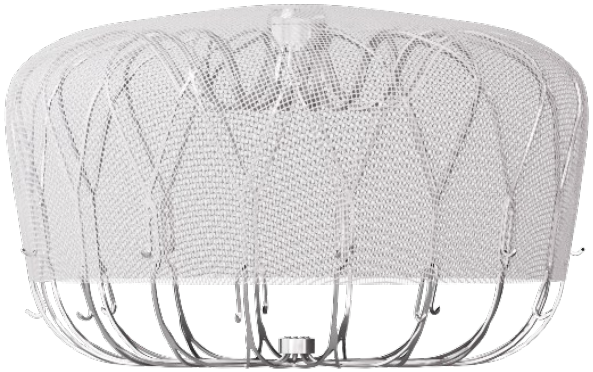
Varosy P et al. JACC 2018; 71(11): A320.

WATCHMAN™

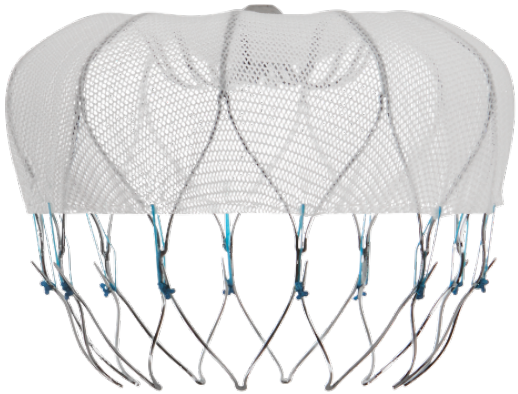
Boston Scientific
Advancing science for life™

Improved Design

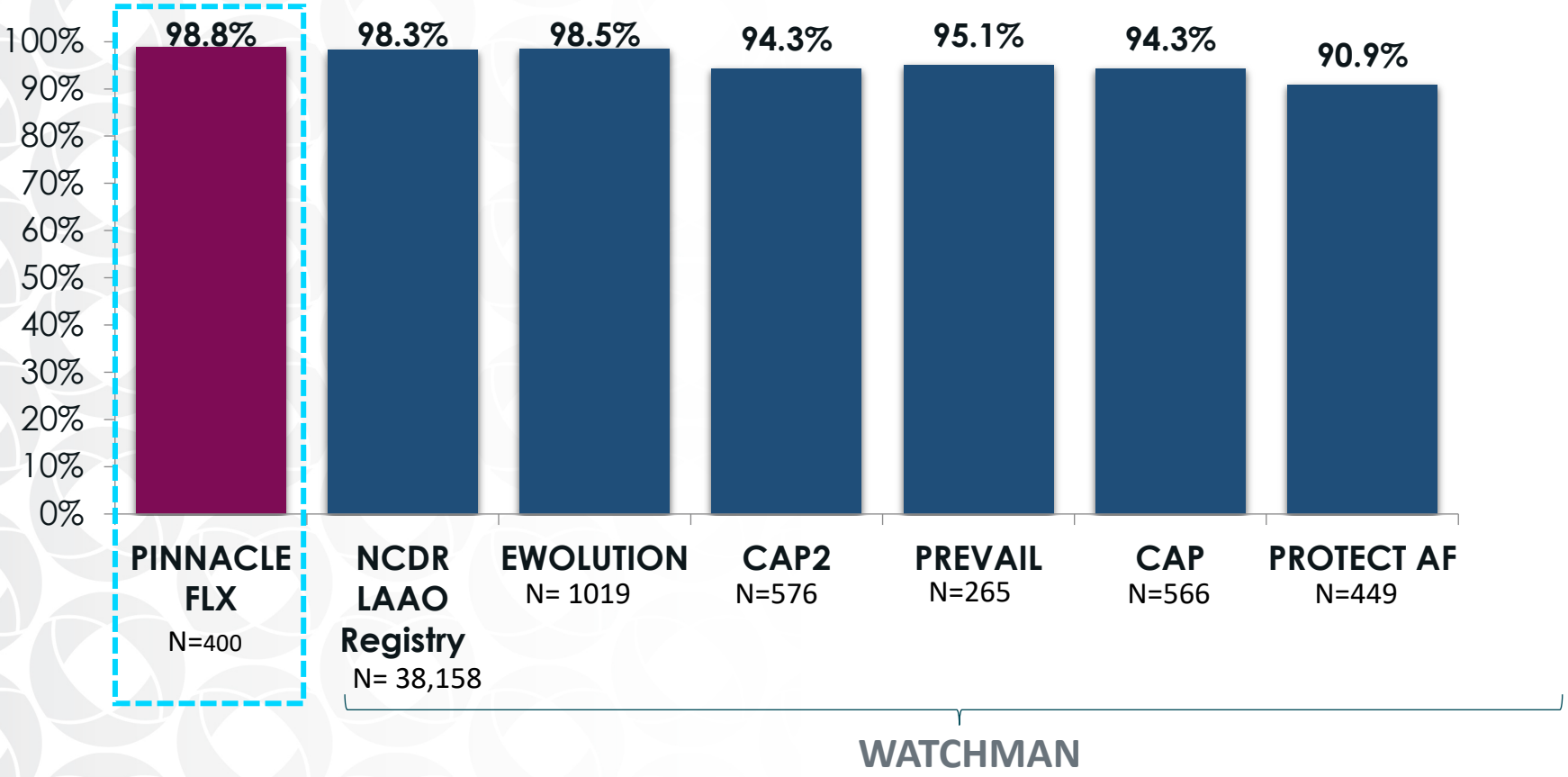
Watchman FLX



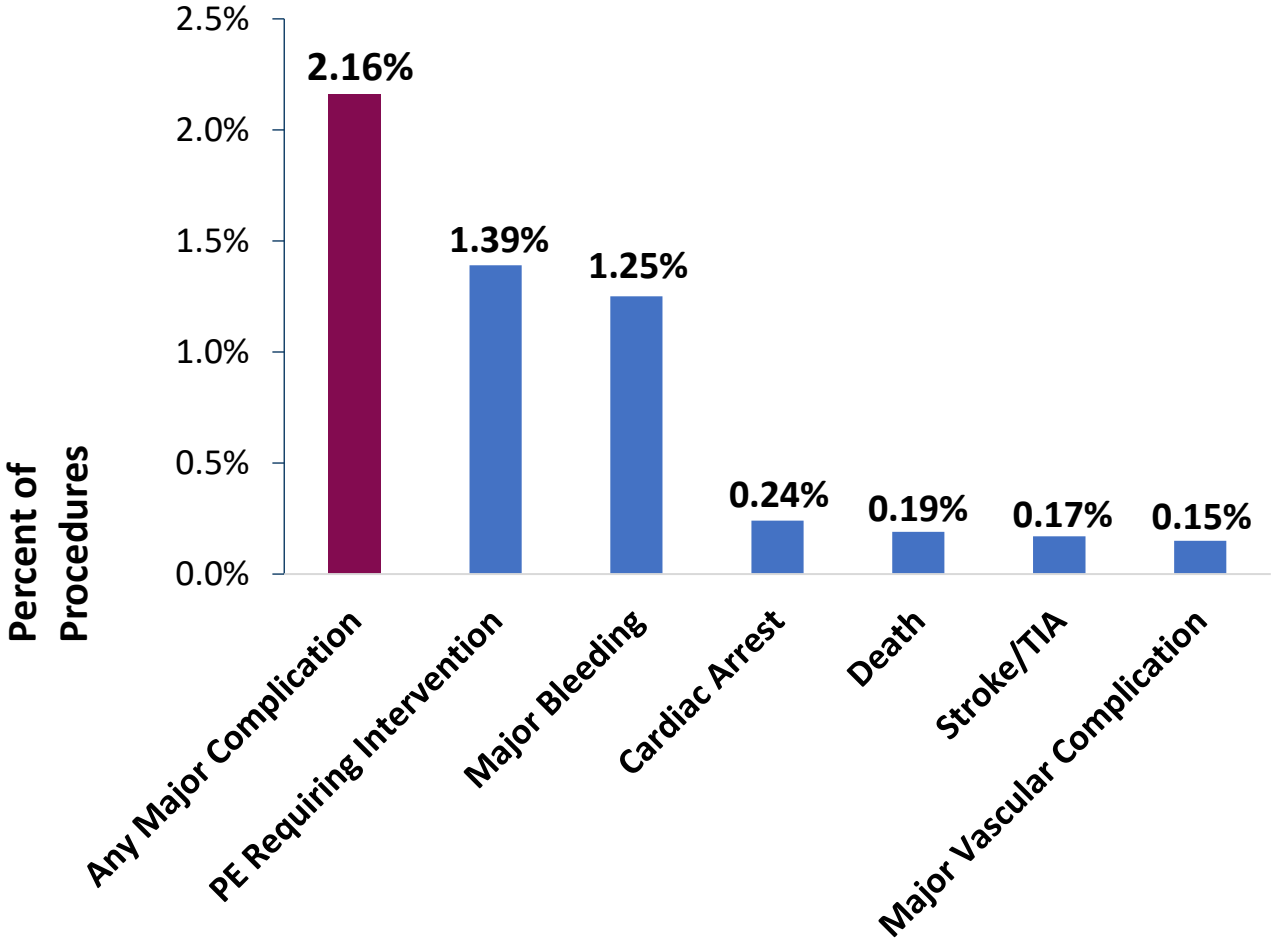
Watchman



WATCHMAN has a High Procedural Success Rate



Major In-Hospital Adverse Events
NCDR LAAO Registry – A Review of the First Three Years



Despite the **high risk** patient profile, **safety compared favorably** with the pivotal trials

In-hospital major adverse event defined as death, cardiac arrest, stroke/TIA, ICH, SE, major bleeding, major vascular complication, myocardial infarction, PE requiring intervention, or device embolization

Freeman JV et al. JACC. 2020;

NCDR® NATIONAL CARDIOVASCULAR DATA REGISTRY

SH-603802-A

Roper St. Francis Watchman Safety

	Watchman 2.5 (n=311)			Watchman FLX (n=144)			Total (n=455)	
Within 7 days:								
Ischemic Stroke:	1	0.30%		0	0.00%		1	0.20%
Pericardial Effusion (Requiring Surgical Intervention)	1	0.30%		0	0.00%		1	0.20%
Pericardial Effusion (requiring percutaneous interventio	3	0.96%		0	0%		3	0.66%
GI Bleed	2	0.60%		2	1.39%		4	0.88%
Device Related Thrombus	0			0			0	
Systemic thromboembolization (other than stroke)	0			0			0	
Intracranial Hemorrhage (other than hemorrhagic stroke)	0			0			0	
TIA	0			0			0	
Undetermined Stroke	0			0			0	
Hemmorhagic Stroke	0			0			0	
Hematoma	0			0			0	
Pulmonary Embolism	0			1	0.69%		1	0.20%
Composite of all-cause death, ischemic stroke, systemic embolism, or device/procedure-related events requiring open cardiac surgery or major endovascular intervention between device implantation and 7 days or hospital discharge (whichever is later)	2	0.60%		0	0%		2	0.40%

Broad Range of Patients Suitable for WATCHMAN

1. History of bleeding
2. Increased bleeding risk based on HAS-BLED score or other factors (e.g. thrombocytopenia, cancer, or risk of tumor associated bleeding in case of systemic anticoagulation)
3. History or risk of falls
4. Documented poor compliance with OAC therapy
5. Inability or difficulty maintaining therapeutic range
6. Occupation that puts patient at an increased bleeding risk
7. Lifestyle or hobby that puts patient at an increased bleeding risk
8. Severe renal failure – medical condition for which OAC inappropriate
9. Avoidance of triple therapy after PCI or TAVR
10. Other situations for which OAC is inappropriate
11. Drug or medication regiment not compatible with oral anticoagulant therapy

ROPER ST. FRANCIS HEALTHCARE

Questions?