Updates in Left Atrial Appendage Occlusion

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Disclosures

I have no relevant disclosures related to this presentation

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Standards and Guidelines

SCAI/HRS Expert Consensus Statement on Transcatheter Left Atrial Appendage Closure

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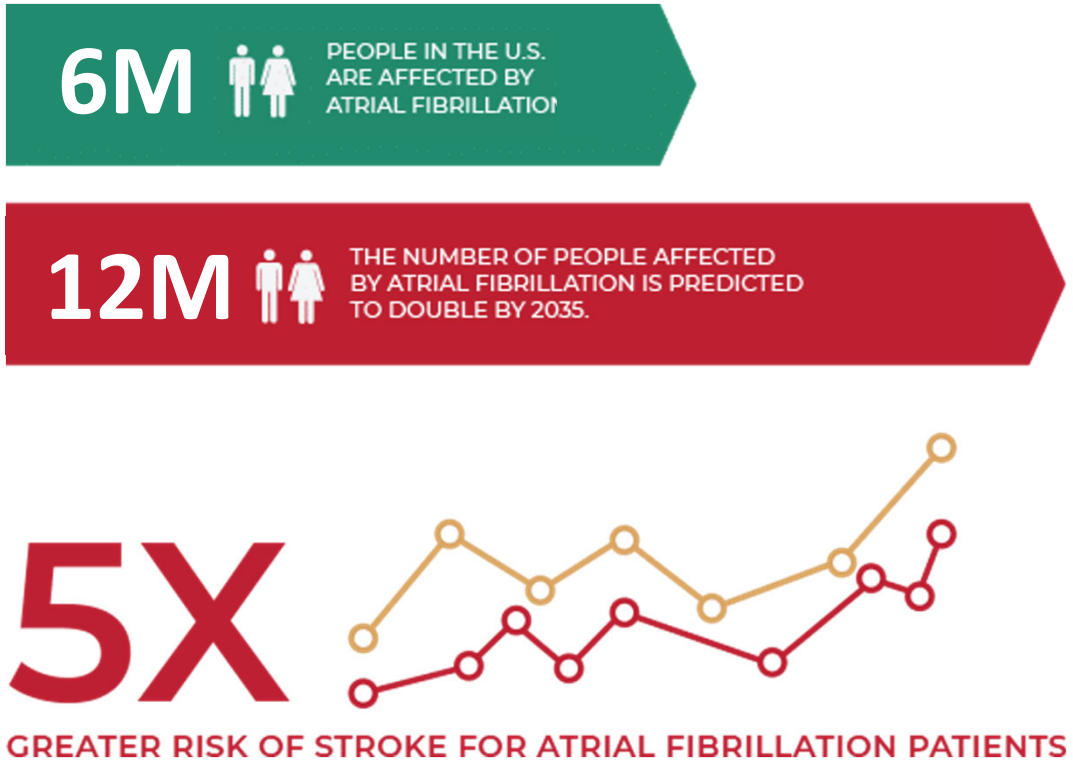
Endorsement: This statement was endorsed by the American College of Cardiology and the Society of Cardiovascular Computed Tomography.

Outline

1. Background
2. Patient Selection
3. Imaging
4. Complications
5. Future directions

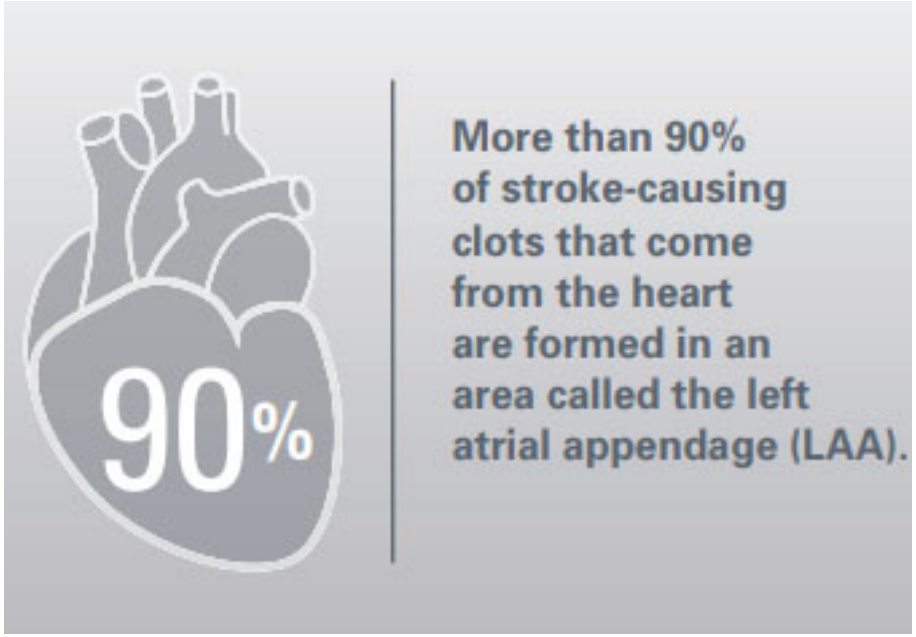
Background

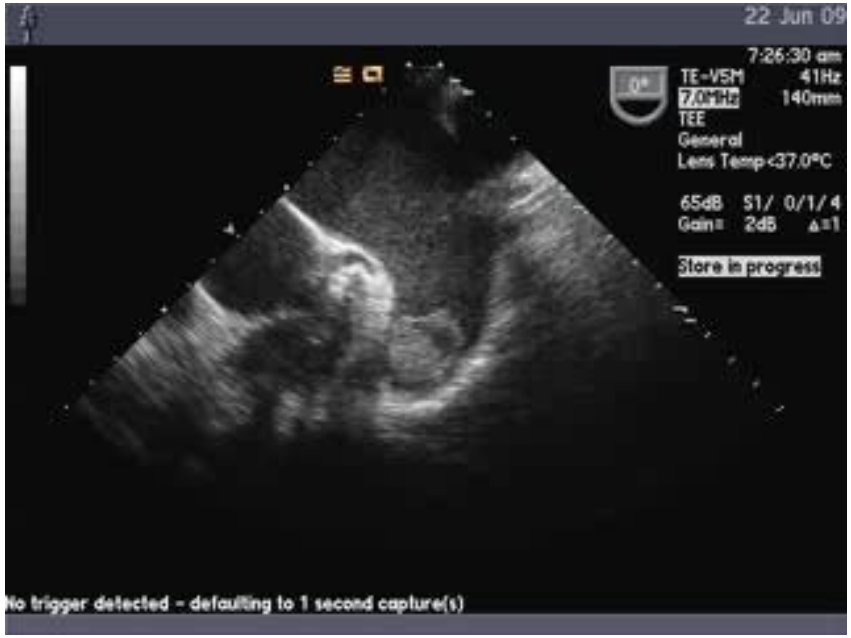


47% of AF patients experiencing a stroke will **suffer a second stroke** within 6 months[4]

Benjamin, EJ et al., Heart Disease and Stroke Statistics. Circulation. 2018; 137: e67-e492.

Background





Holmes DR, Atrial Fibrillation and Stroke Management: Present and Future, Seminars in Neurology 2010;30:528–536

Background

2014 ACC/AHA/HRS Treatment Guidelines to Prevent Thromboembolism in Patients with AF & 2019 Focused Update

Balance stroke risk reduction benefit vs. bleeding risk

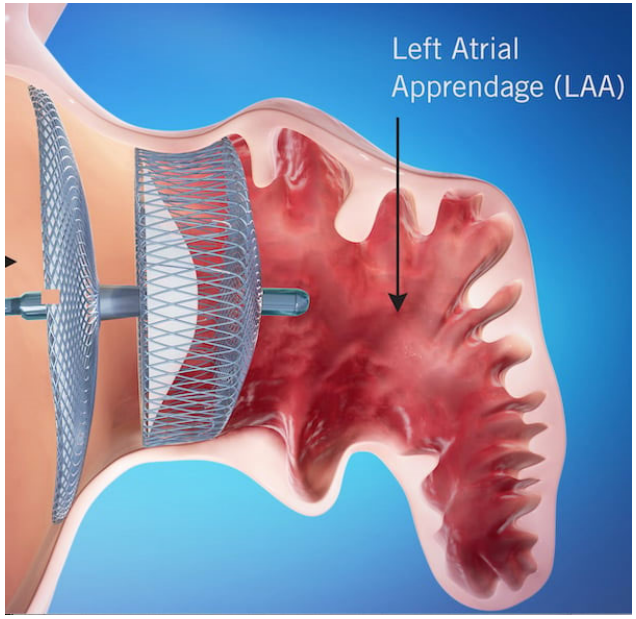
CHA_2DS_2-VASc Score in Men	CHA_2DS_2-VASc Score In Women	Recommendation
0	0	No anticoagulant
1	2	Aspirin (81-325 mg daily) or oral anticoagulants may be considered*
≥ 2	≥ 3	Oral anticoagulants are recommended**

Background

Long-Term Oral Anticoagulation is Not Ideal for All NVAF Patients

Warfarin	Direct Oral Anticoagulants
Bleeding Risk	Bleeding Risk
Daily Regimen	Daily Regimen
High Non-Adherence Rates	High Non-Adherence Rates
Regular INR Monitoring	Complicate Surgical Procedures
Food & Drug Interaction Issues	Drug Interaction Issues
Complicate Surgical Procedures	High Cost

Background



AMULET

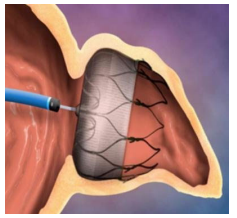
WATCHMAN 2.5

WATCHMAN FLX

Background

Table 1 Summary of important trials of percutaneous left atrial appendage occlusion and associated limitations

Trial	Study arms	Sample size	Outcomes of interest	Results
PROTECT AF[15]	LAAO using first-generation Watchman vs warfarin, 2:1 randomization, noninferiority study design	707	(1) Primary efficacy endpoint = composite of stroke, SE, and CV/unexplained deaths (2) Primary safety endpoint = composite of significant bleeding or procedure-related complications (serious pericardial effusion, device embolization, and procedure-related stroke)	(1) LAAO noninferior for the efficacy endpoint (95% credible interval 0.35–1.25, criteria for noninferiority <2) (2) High rate of significant pericardial effusion (4.8%), procedural stroke (1.1%), and embolization (0.6%) in the LAAO arm
PREVAIL[16]	LAAO using first-generation Watchman vs warfarin, 2:1 randomization, noninferiority study design	407	(1) First primary efficacy endpoint = composite of all stroke, SE, and CV/unexplained deaths (2) Second primary efficacy endpoint = composite of ischemic stroke and SE 7 days after implantation (3) Primary safety endpoint = composite of all-cause death, ischemic stroke, SE, and procedure-related complications within 7 days of implantation	(1) LAAO was inferior for the first primary efficacy endpoint (95% credible interval 0.57–1.89, criteria for noninferiority <1.75) (2) LAAO was noninferior for the second primary efficacy endpoint (rate difference -0.0190 to 0.0273, criteria for noninferiority <0.0275) (3) Safety events 2.2% in the LAAO arm
PINNACLE FLX[17]	Single arm (LAAO using Watchman FLX)	400	(1) Primary efficacy endpoint = effective closure (device leak of ≤5 mm at 1 year) (2) Primary safety endpoint = death, ischemic stroke, SE, or device-related major events requiring surgery or endovascular interventions within 7 days of implant	(1) Incidence of primary efficacy endpoint was 100%, which exceeds performance goal of 97% (2) Incidence of primary safety endpoint was 0.5% with 95% upper CI of 1.6, meeting the performance goal of <4.21



WATCHMAN 2.5

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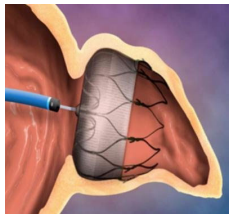

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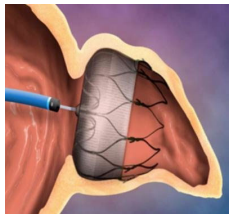

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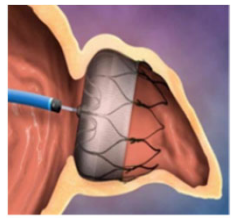
AMULET



WATCHMAN 2.5

WATCHMAN FLX

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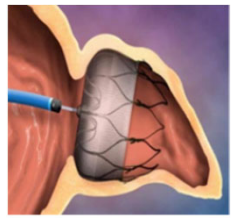

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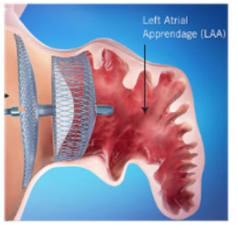
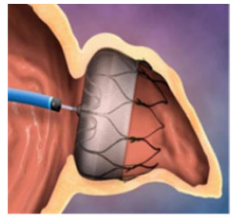


61% AMULET



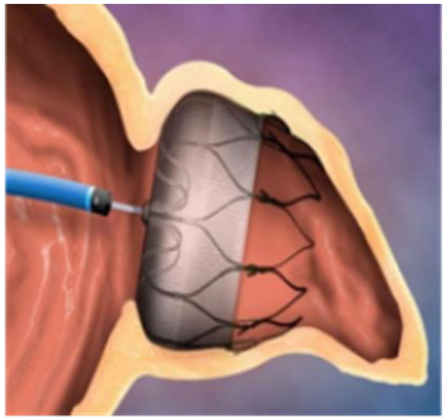
36% WATCHMAN 2.5

3% WATCHMAN FLX

Background

FDA APPROVED

2015

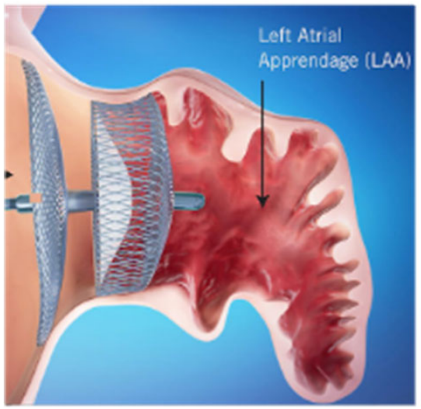


WATCHMAN 2.5

2020

WATCHMAN FLX

2021

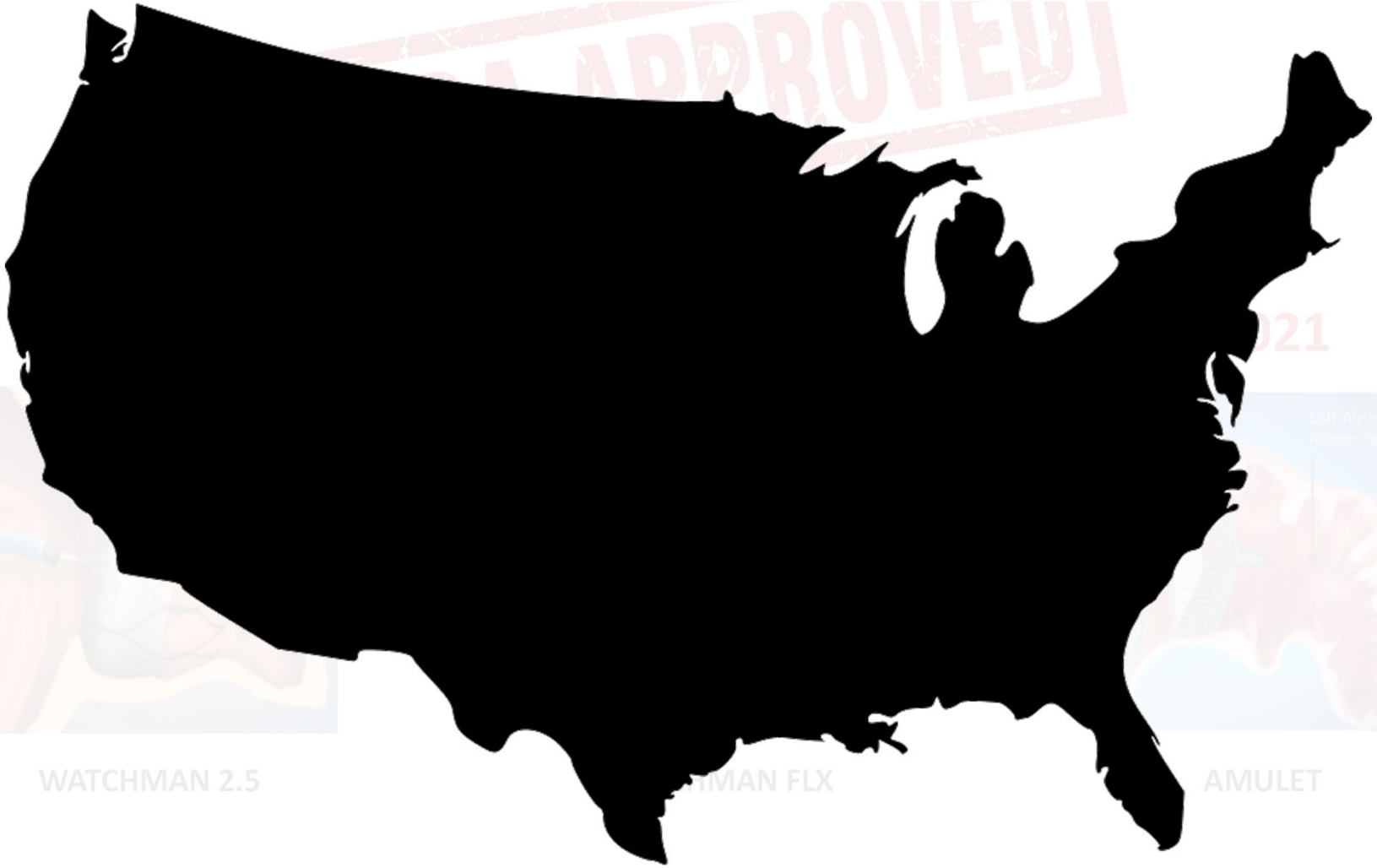


AMULET

2023

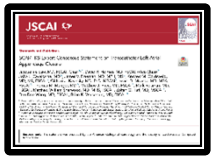
WATCHMAN FLX Pro

Background



Patient Selection

Patient Selection



Transcatheter LAAC is appropriate for patients with **nonvalvular AF with high thromboembolic risk** who are **not suited for long-term OAC** and who have **adequate life expectancy** (minimum >1 year) and quality of life to benefit from LAAC. **There should be patient-provider discussion for shared decision making.**

CHA_2DS_2VASc SCORE
(STROKE RISK)

	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
Sc	Sex Category (Female)	1
A	Age 65-74 Years	1
TOTAL POINTS		

SCORE	YEARLY STROKE RISK (%)
0	0
1	1.3
2	2.2
3	3.2
4	4.0
5	6.7
6	9.8
7	9.6
8	6.7
9	15.2

HAS-BLED SCORE
(BLEEDING RISK WITH WARFARIN)

	CONDITION	POINTS
H	Hypertension	1
A	Abnormal Renal/Liver Function (1 point each)	1 or 2
S	Hemorrhagic Stroke	1
B	Bleeding History of Disposition	1
L	Labile	1
E	Elderly	1
D	Current Drugs (medication)/Alcohol Use (1 point each)	1 or 2
TOTAL POINTS		

SCORE	YEARLY MAJOR BLEEDING RISK (%)
0	1.13
1	1.02
2	1.88
3	3.74
4	8.7
5+	12.5

Imaging

Imaging

Pre-Procedural

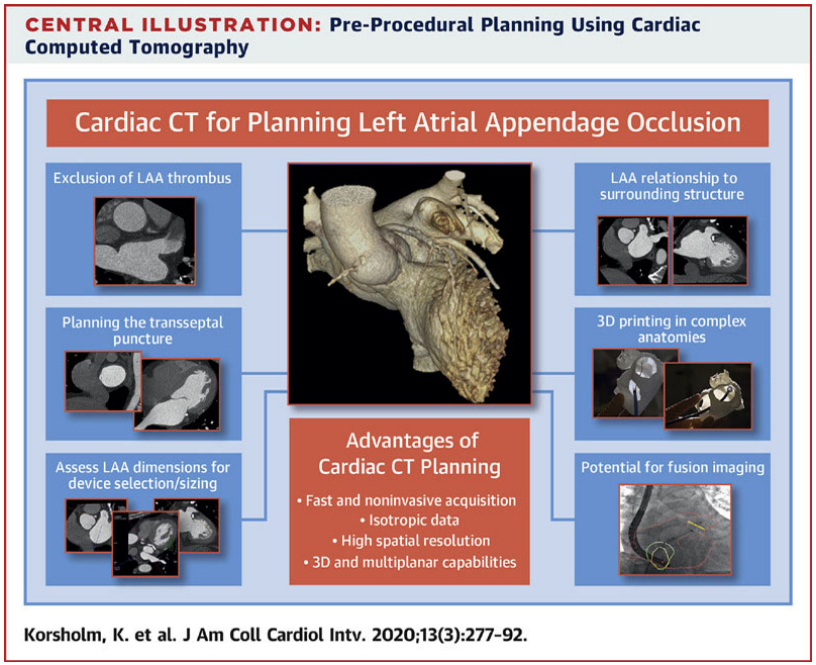
Intra-Procedural

Post-Procedural

Imaging

Pre-Procedural

Baseline preprocedural imaging with **TEE** or **cardiac computed tomography angiography** is recommended before LAAC



Imaging

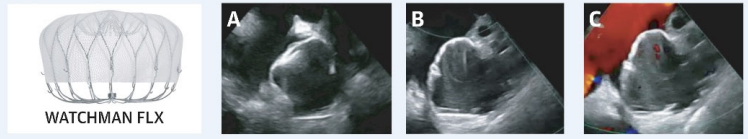
Intra-Procedural

Intraprocedural imaging guidance with **TEE or ICE** and **contrast angiography** is strongly recommended

CENTRAL ILLUSTRATION: Intracardiac Echocardiography (ICE) to Guide Watchman FLX Implantation

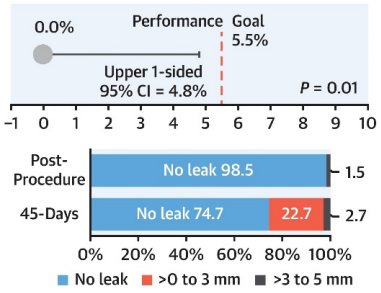
The ICE LAA Clinical Study

Goal: Assess ICE to guide implantation of the WATCHMAN FLX



Primary Endpoint

Significant peridevice leak (>5 mm) at 45 days



45-Day Clinical Outcomes

	Patients % (n/N)
Mortality	1.0 (1/100)
Stroke	0 (0/100)
Systemic Embolism	0 (0/100)
Major Bleeding	3.1 (3/100)
Nonprocedural Major Bleeding	2.1 (2/100)
Pericardial Effusion	0 (0/100)
Device Embolization	0 (0/100)
Device-Related Thrombus	0 (0/100)

Nielsen-Kudsk JE, et al. J Am Coll Cardiol Intv. 2023;16(6):643-651.

Imaging

Post-Procedural

Table 5. Imaging surveillance modality and optimal imaging at different postdevice implantation time points.

Imaging timing	Immediate postdevice implant	Prehospital discharge	45-d follow-up	1-y follow-up (optional)
Transthoracic echocardiogram	–	+++	–	–
Transesophageal echocardiogram	+++	–	++	++
CCTA	–	–	+++	+++
Complication surveillance	**Pericardial effusion**	**Device embolization**	**Peridevice leak**	**Device-related thrombus**
Transthoracic echocardiogram	+++	+	–	–
Transesophageal echocardiogram	+++	+++	++	+++
CCTA	+++	+++	+++	+++

+++, strongly recommended; ++, less strongly recommended; +, recommended; –, not required.
CCTA, cardiac computed tomography angiography.

Complications

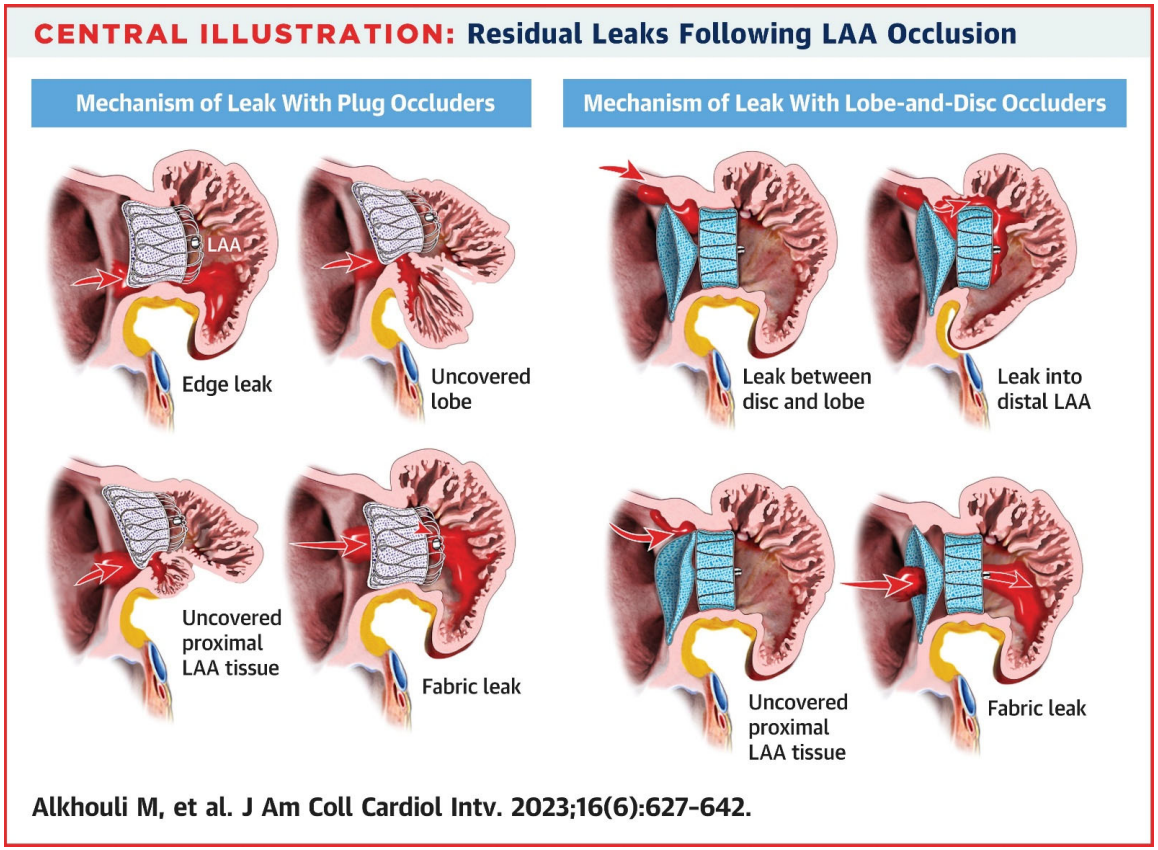
Complications

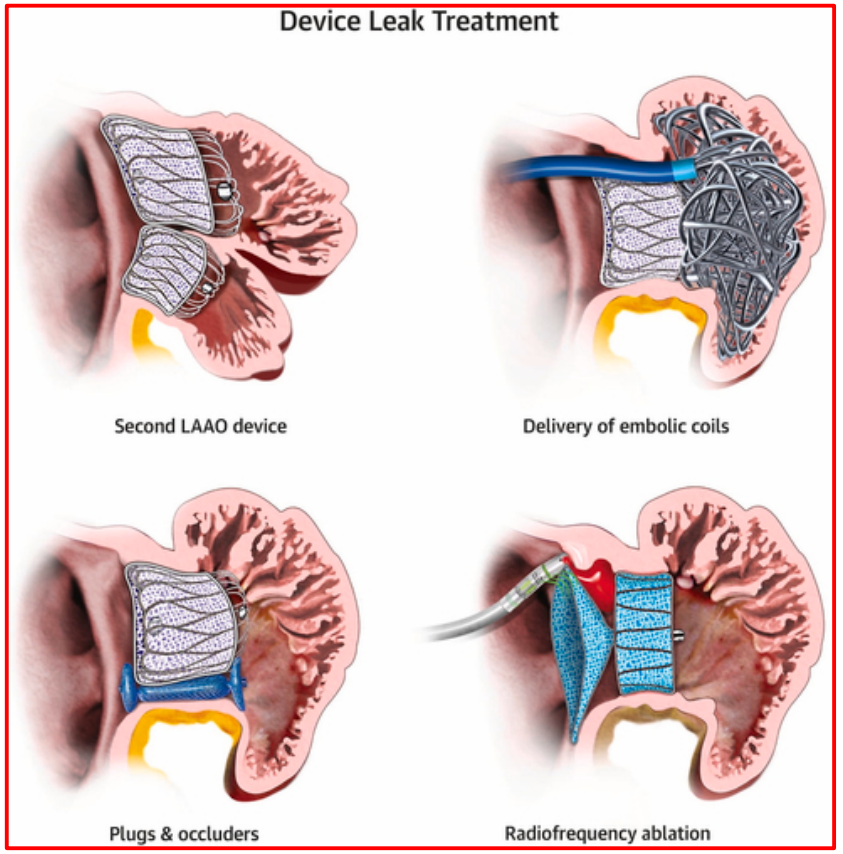
Table 4. Procedural and late postprocedural complications of left atrial appendage occlusion.

Periprocedural complications	Postprocedural complications
Death (<0.2%)	Late pericardial effusion & tamponade (~1%)
Stroke (<0.2%): Ischemic: air or thromboembolism Hemorrhagic	Peridevice leak: >5 mm on TEE: 1%-3% >3 mm on TEE: 10%-25%
Systemic embolism (rare)	Device-related thrombus (3%-5%)
Pericardial tamponade (~1%)	Late device migration/ embolization (infrequent)
Device embolization (~0.2%)	Device erosion (rare)
Vascular complications: retroperitoneal bleed, arteriovenous fistula, pseudoaneurysm	Iatrogenic atrial septal defects (rare to require intervention)
Other: major bleeding, renal failure, respiratory failure, sepsis, MI, endotracheal/esophageal damage, interfering surrounding structures, device/contrast allergy, pericarditis	

MI, myocardial infarction; TEE, transesophageal echocardiography.

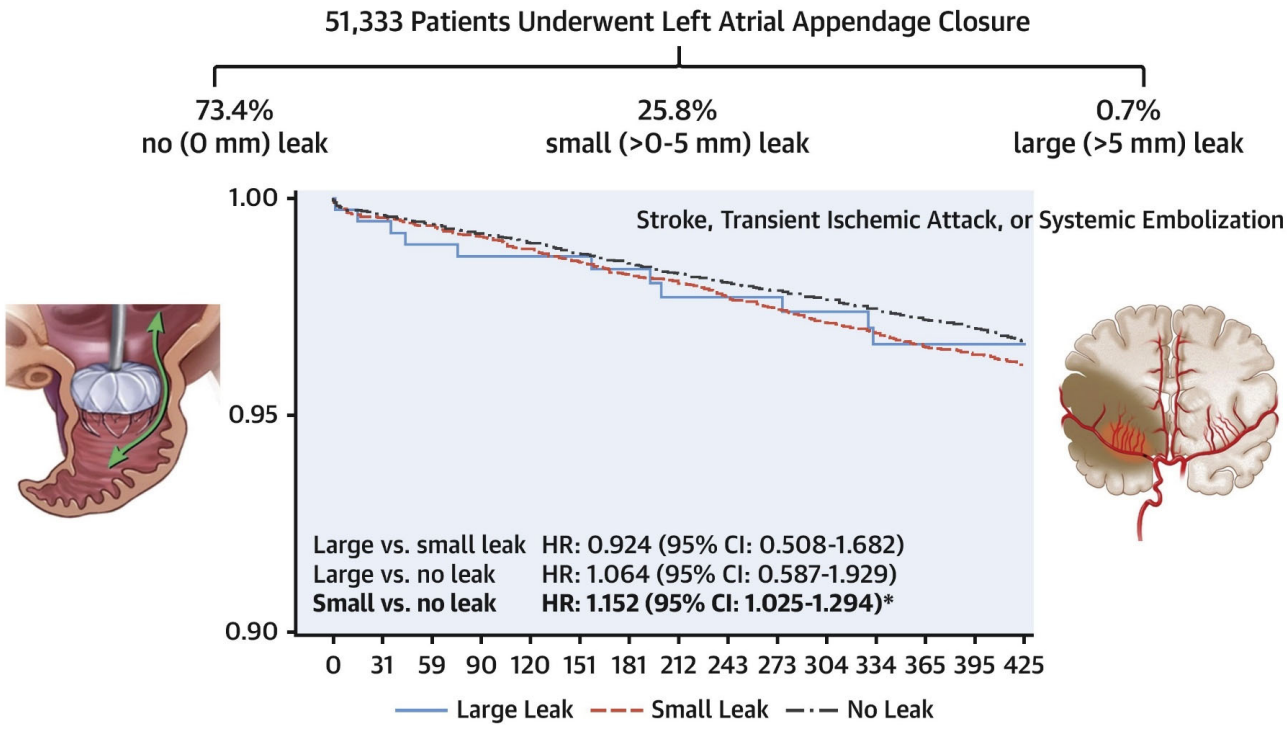
Complications





Complications

CENTRAL ILLUSTRATION: Association of Peri-Device Leak With Thrombo-embolic Events After Left Atrial Appendage Occlusion



Alkhouli M, et al. J Am Coll Cardiol EP. 2022;8(6):766-778.

Complications

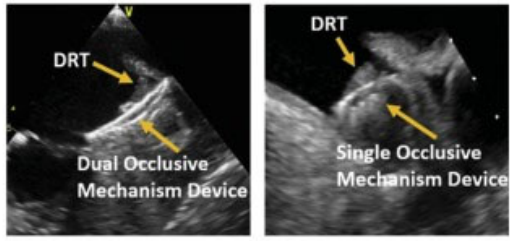
Table 4. Procedural and late postprocedural complications of left atrial appendage occlusion.

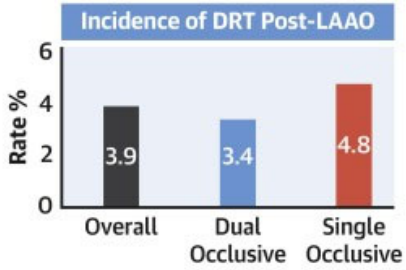
Periprocedural complications	Postprocedural complications
Death (<0.2%)	Late pericardial effusion & tamponade (~1%)
Stroke (<0.2%): Ischemic: air or thromboembolism Hemorrhagic	Peridevice leak: >5 mm on TEE: 1%-3% >3 mm on TEE: 10%-25%
Systemic embolism (rare)	Device-related thrombus (3%-5%)
Pericardial tamponade (~1%)	
Device embolization (~0.2%)	Late device migration/ embolization (infrequent)
Vascular complications: retroperitoneal bleed, arteriovenous fistula, pseudoaneurysm	Device erosion (rare)
Other: major bleeding, renal failure, respiratory failure, sepsis, MI, endotracheal/esophageal damage, interfering surrounding structures, device/contrast allergy, pericarditis	Iatrogenic atrial septal defects (rare to require intervention)

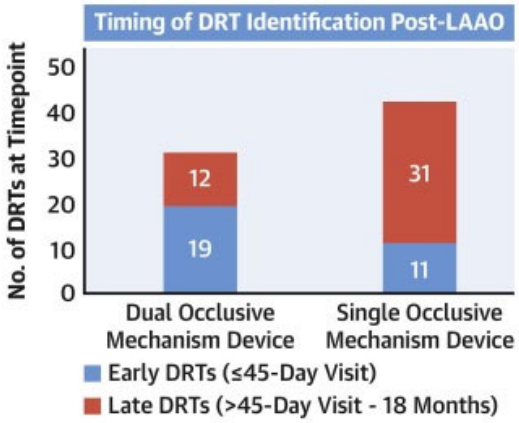
MI, myocardial infarction; TEE, transesophageal echocardiography.

Complications

CENTRAL ILLUSTRATION: DRT After LAAO With the Dual Occlusive Mechanism Device Versus the Single Occlusive Mechanism Device





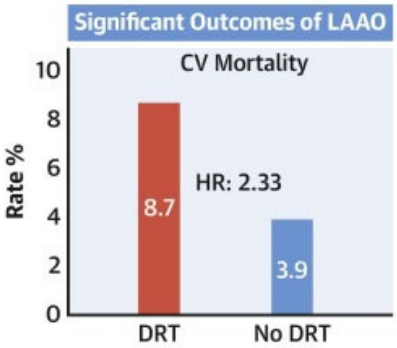


Strong Predictors

- AF rhythm at procedure
- Females
- Older Age

Trending Predictors

- Nonparoxysmal AF
- Increased CHA_2DS_2-VASc
- Heart failure (NYHA)



Schmidt B, et al. J Am Coll Cardiol EP. 2023;9(1):96-107.

Future Directions

Future Directions

Table 1. Ongoing endovascular LAAC randomized controlled trials and postprocedural antithrombotic strategies.

	OAC-eligible patients			OAC-contraindicated patients		
Trial	OPTION trial: WATCHMAN FLX vs OAC after PV ablation	CHAMPION-AF trial: WATCHMAN FLX vs DOAC	CATALYST trial: Amulet vs DOAC	ASAP-TOO trial: WATCHMAN vs control	STROKE-CLOSE trial: Amulet vs control	CLOSURE-AF trial: LAAC vs OAC
N	1600	3000	2650	888[a]	750	1512
Postprocedural antithrombotic strategies	DOAC or warfarin and aspirin for 3 mo after LAAC	DOAC and aspirin or DAPT for 3 mo after LAAC	DAPT for 3 mo after LAAC	DAPT for 3 mo after LAAC	Aspirin ± clopidogrel for 45 d after LAAC	DAPT after LAAC
Control	OAC	DOAC	DOAC	Aspirin or none	OAC, antiplatelet, or none	DOAC or warfarin

DAPT, dual antiplatelet therapy; DOAC, direct oral anticoagulation; LAAC, left atrial appendage closure; OAC, oral anticoagulation; PV, pulmonary vein.

[a] Study stopped prematurely (~500 patients enrolled).

Future Directions

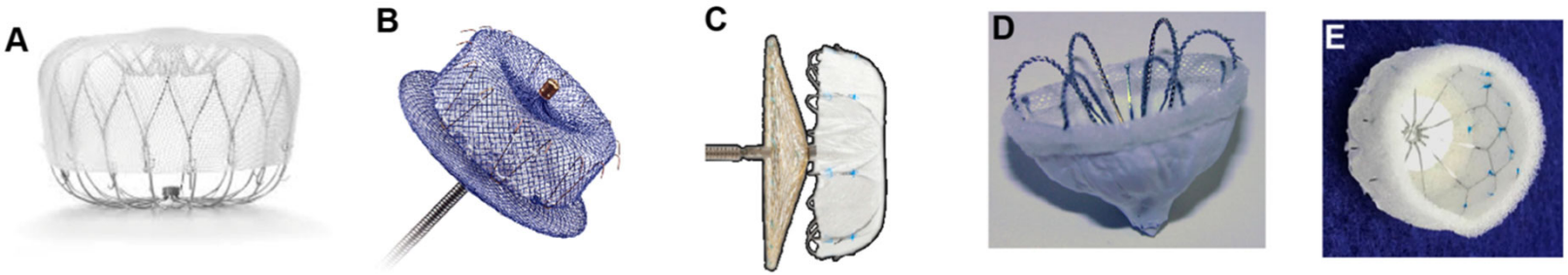


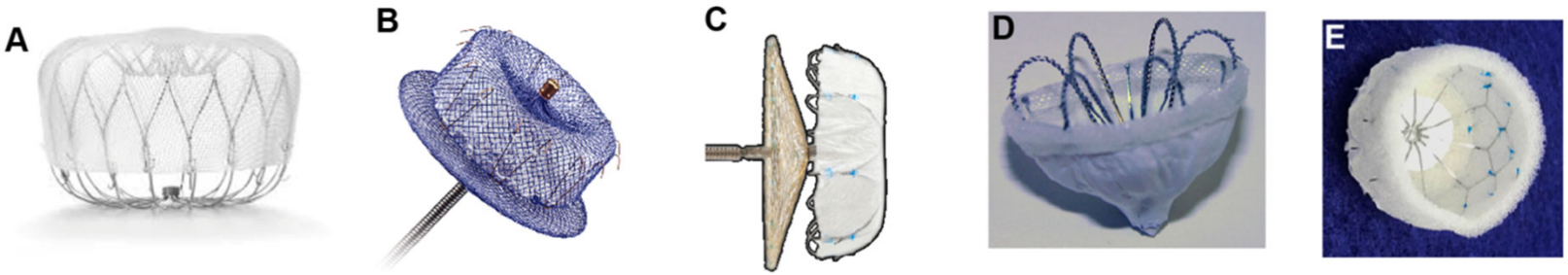
Figure 1.

Examples of transcatheter LAAC devices. (**A**) WATCHMAN FLX, (**B**) Amulet, (**C**) LAmbre, (**D**) Wavecrest, and (**E**) Conformal. LAAC, left atrial appendage closure.

Thank You!

Owensboro Health

Future Directions



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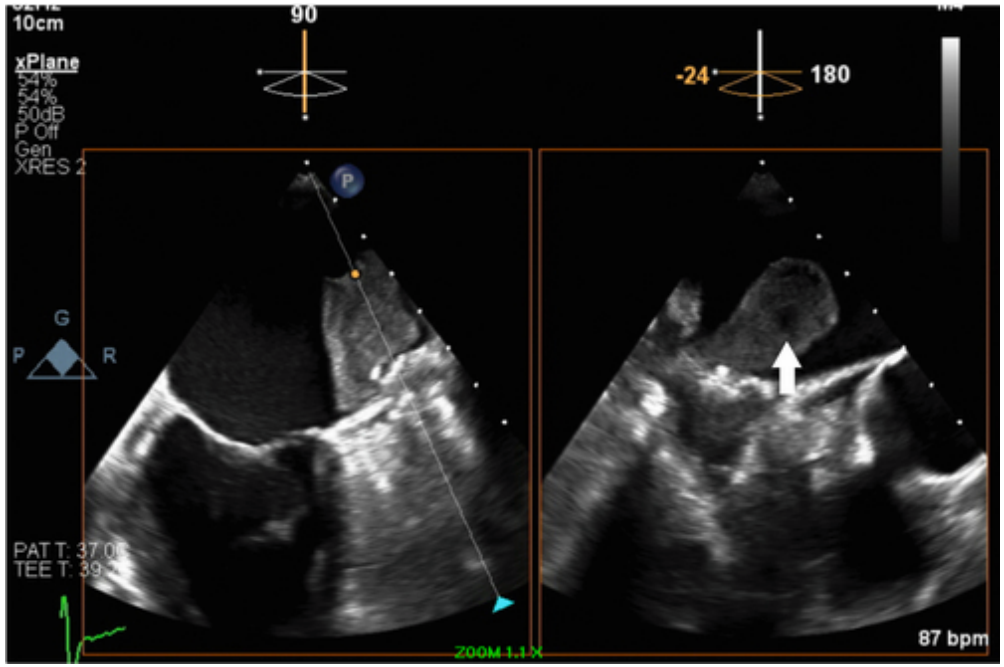

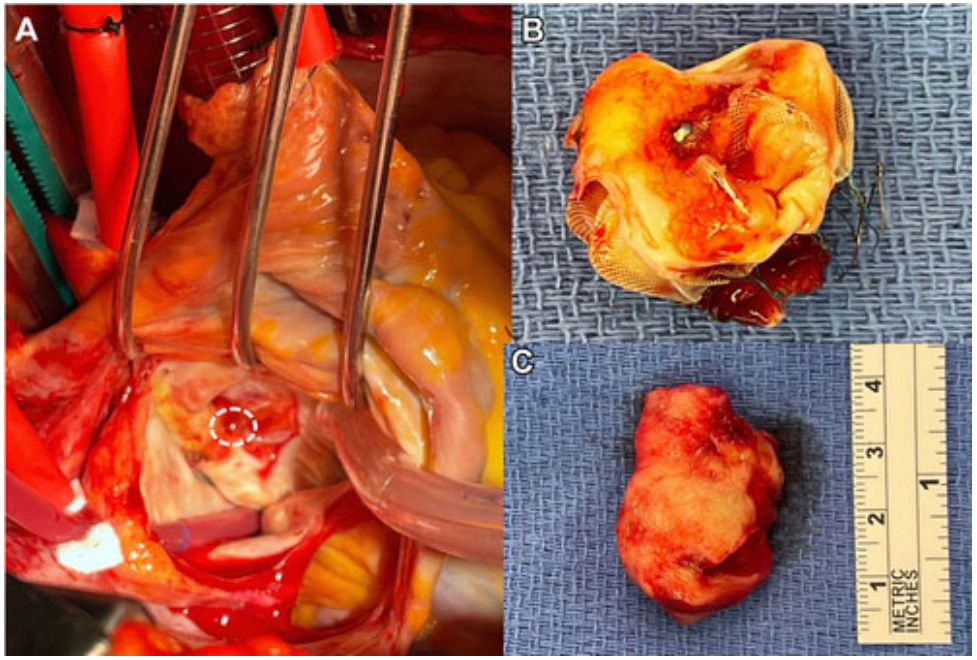

Damir Vukomanovic et al., J Am Coll Cardiol Case Rep. 2022 Nov, 4 (21) 1409–1413

Background

Table 2. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation.

Recommendations	Class of recommendation	Level of evidence
After surgical occlusion or exclusion of the LAA, it is recommended to continue anticoagulation in at-risk patients with AF for stroke prevention	I	B
LAA occlusion may be considered for stroke prevention in patients with AF and contraindications for long-term anticoagulant treatment (eg, those with a previous life-threatening bleed without reversible cause).	IIb	B
Surgical occlusion or exclusion of the LAA may be considered for stroke prevention in patients with AF undergoing cardiac surgery.	IIb	B
Surgical occlusion or exclusion of the LAA may be considered for stroke prevention in patients undergoing thoracoscopic AF surgery.	IIb	B

ACC, American College of Cardiology; AF, atrial fibrillation; AHA, American Heart Association; HRS, Heart Rhythm Society; LAA, left atrial appendage.
Adapted from January et al.[19]

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COMPLIACATIONS/ADVERSE EVENTS

2.1. Physician initial requirements: >50 prior left-sided ablations or structural procedures and >25 transseptal punctures
2.2. Skill maintenance: >25 transseptal punctures and >12 LAACs over 2 years
2.3. Institutional requirements: on-site cardiovascular surgery (CVS) program backup during implanter's early learning curve

Patient Selection

2.Physician and Institutional Requirements.

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