LA CHIUSURA DELL'AURICOLA
NELLA PREVENZIONE
DELL' EMBOLIA CARDIOGENA

Parma 21 Gennaio 2014

LEFT ATRIAL APPENDAGE CLOSURE

Descrizione della tecnica

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AF and Stroke

3 million in US and 4.5 million in the EU have AF[1]

2/3 of AF population are at high-risk of stroke[1]

35% of patients with AF will have a stroke in their lifetime[2]

AF is responsible for 15-20% of ischemic strokes[1]

AF Incidence increases with age[2]

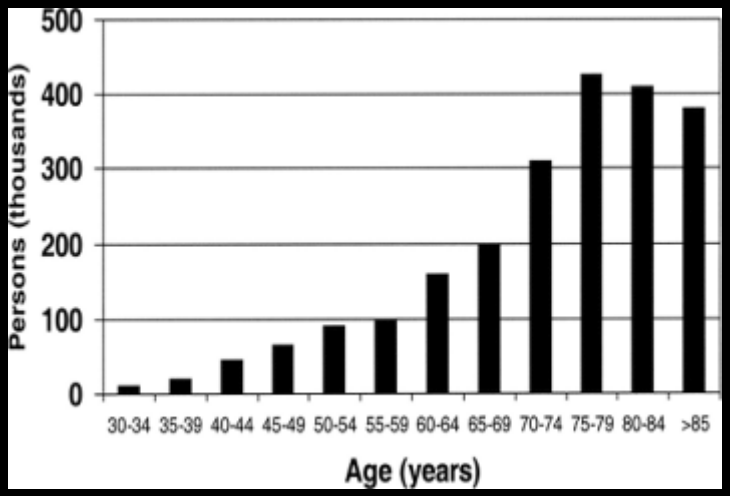
0.4% in general population

0.2% of 25-34 yrs of age

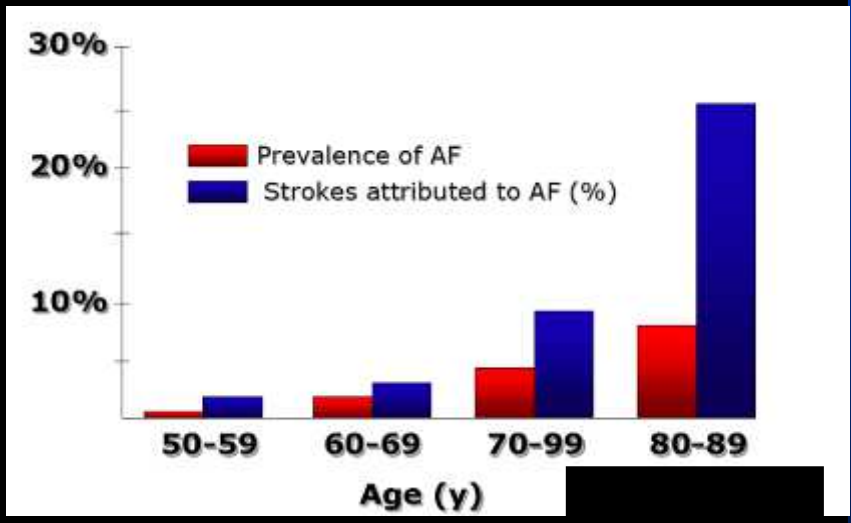
2-5% of >60 yrs of age

20% of > 80 yrs of age

Estimated age-specific AF prevalence[2]



Relationship of AF and stroke[2]



[1] Fuster et al., ACC/AHA/ESC Practice Guidelines, Circulation. 2006;114:700-752

[2] Wolf PA et al., Atrial fibrillation as an independent risk factor for stroke: the Framingham study. Stroke 1991;22:983–8

STROKE

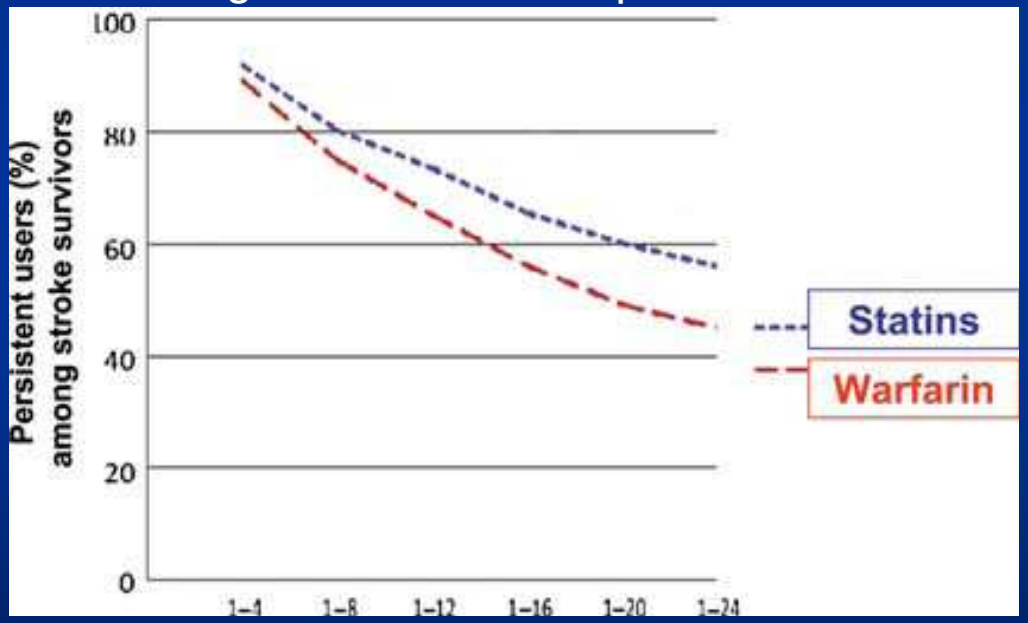
The percentage of strokes attributable to atrial fibrillation increase steeply from 1.5% at 50–59 years of age to more than 20% at 80–89 years of age.

The LAA has been the site in the left atrium where more than 90% of thrombi were detected in patients with non-valvular atrial fibrillation in transoesophageal studies.

Stroke prevention in patients with atrial fibrillation has largely been based on the use of anticoagulation with warfarin, which reduces the risk of stroke by 60%.

STROKE

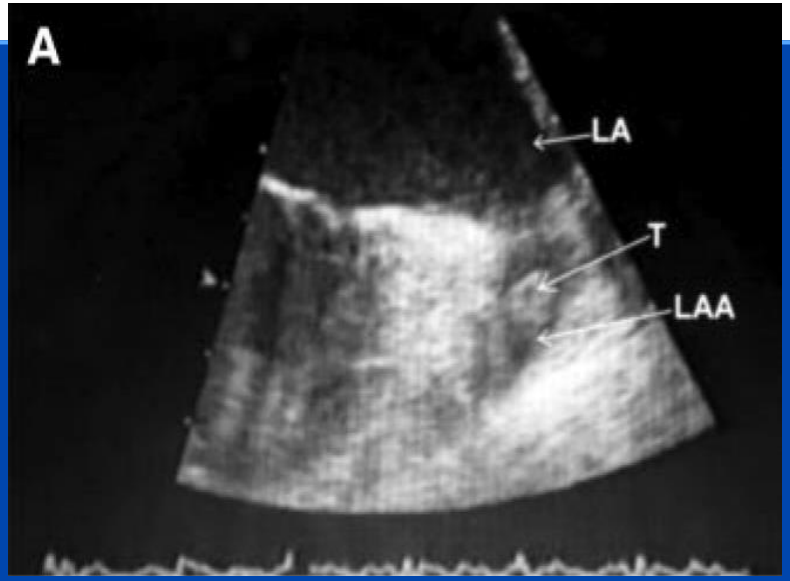
A significant proportion of patients with atrial fibrillation, ranging from 30 to 50%, do not receive anticoagulation due to relative or absolute contraindications or due to patient- and/or physician pertinent barriers limiting the use of anticoagulation in clinical practice

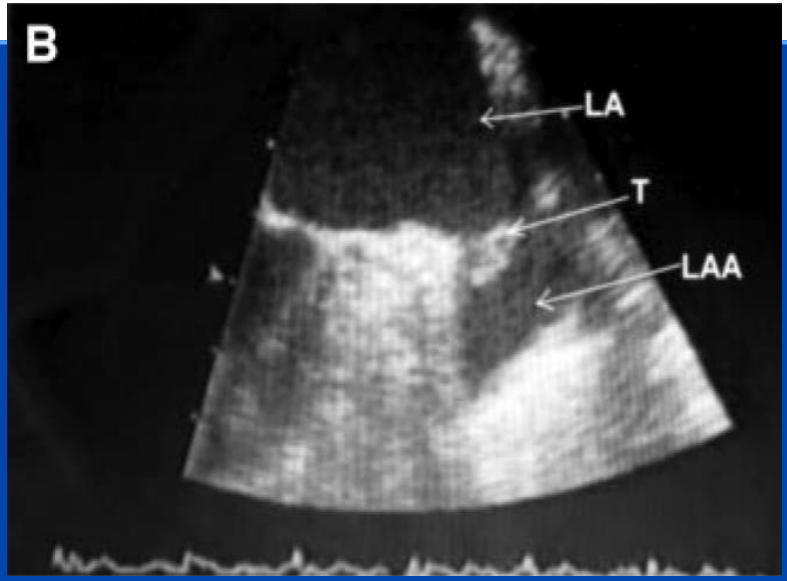


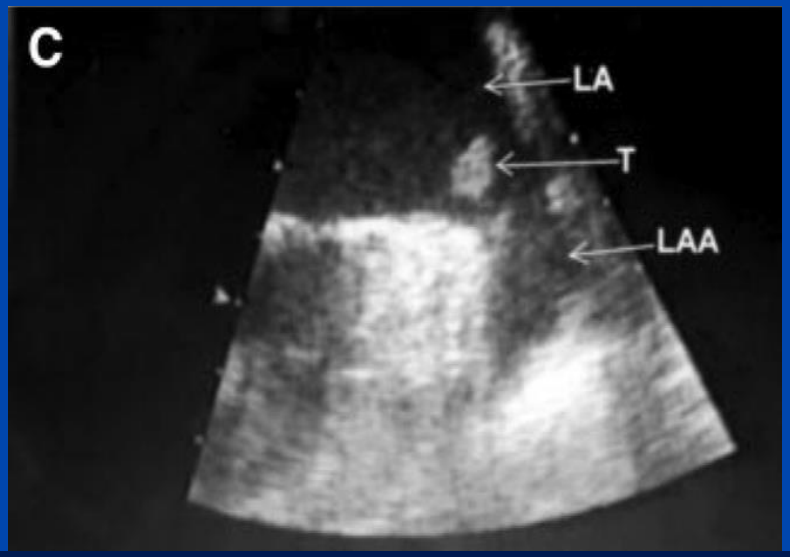
The persistent use of anticoagulation with warfarin prescribed for secondary prevention after stroke was observed to decline to 45% after 2 years

Striking a fine balance

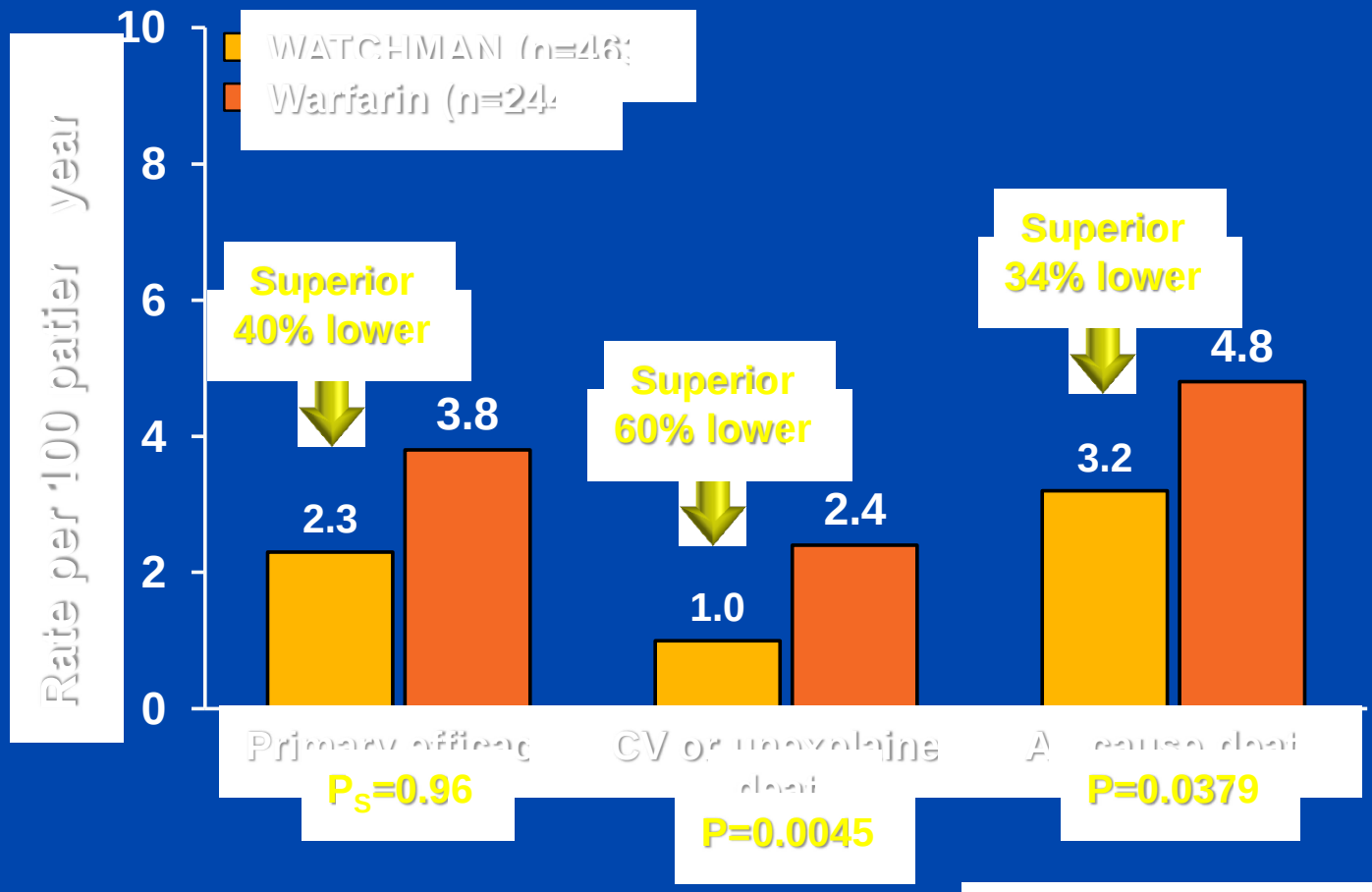
Disappearing LAA Thrombus Resulting in Stroke







Background
PROTECT AF 4-Year Superiority



P_S = Posterior Superiority Probability
Reddy et al: HRS, 2013

MAYO CLINIC

New Entries in the ESC Guidelines for the Management of Atrial Fibrillation (AF)[1]

Recommendation for Left Atrial Appendage Occlusion (LAAO)

The European Society of Cardiology has released the 2012 focused update on the guidelines for the management of atrial fibrillation. This update includes for the first time a recommendation for the use of left atrial appendage occlusion.

The update was developed with contribution from the European Heart Rhythm Association (EHRA).

Recommendations for LAA closure/occlusion/excision

Recommendations	Class[a]	Level[b]	Ref[c]
Interventional, percutaneous LAA closure may be considered in patients with a high stroke risk and contraindications for long-term oral anticoagulation.	IIb	B	115, 118
Surgical excision of the LAA may be considered in patients undergoing open heart surgery.	IIb	C	

LAA = left atrial appendage.
[a]Class of recommendation.
[b]Level of evidence.
[c]References.

- "Interventional percutaneous occlusion/closure of the LAA has a role in patients with thromboembolic risk who cannot be managed in the long-term using any form of OAC."[1]

Source: Camm A, Lip G, De Caterina R, et al. "2012 focused update of the ESC Guidelines for the management of atrial fibrillation." *Eur Heart J.* Presented ahead of publication European Society of Cardiology Congress; 2012 August 25-29; Munich, Germany.

RegioneEmilia-Romagna

AGENZIA SANITARIA E SOCIALE REGIONALE

COMMISSIONE CARDIOLOGICA E CARDIOCHIRURGICA REGIONALE

DOCUMENTO DI INDIRIZZO

CHIUSURA PERCUTANEA DELL'AURICOLA SINISTRA MEDIANTE DEVICE ENDOCAVITARIO

Data di pubblicazione: settembre 2012

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Indicazioni d'uso appropriato

Il Gruppo di Lavoro, sulla base della propria esperienza clinica e dei risultati della letteratura disponibile, ritiene di raccomandare la chiusura percutanea dell'auricola sinistra nei pazienti con FA cronica con le seguenti finalità:

- **prevenzione primaria di evento ischemico in:**
  - pazienti con indicazione a TAO che presentino tuttavia controindicazioni assolute a tale terapia;
  - pazienti con indicazione a TAO che hanno presentato un episodio di sanguinamento maggiore da causa non rimovibile durante TAO ben condotta
- **prevenzione secondaria di evento ischemico in:**
  - pazienti che hanno presentato un ictus durante TAO in range terapeutico, dopo workup diagnostico che abbia escluso la presenza di altre sorgenti emboligene

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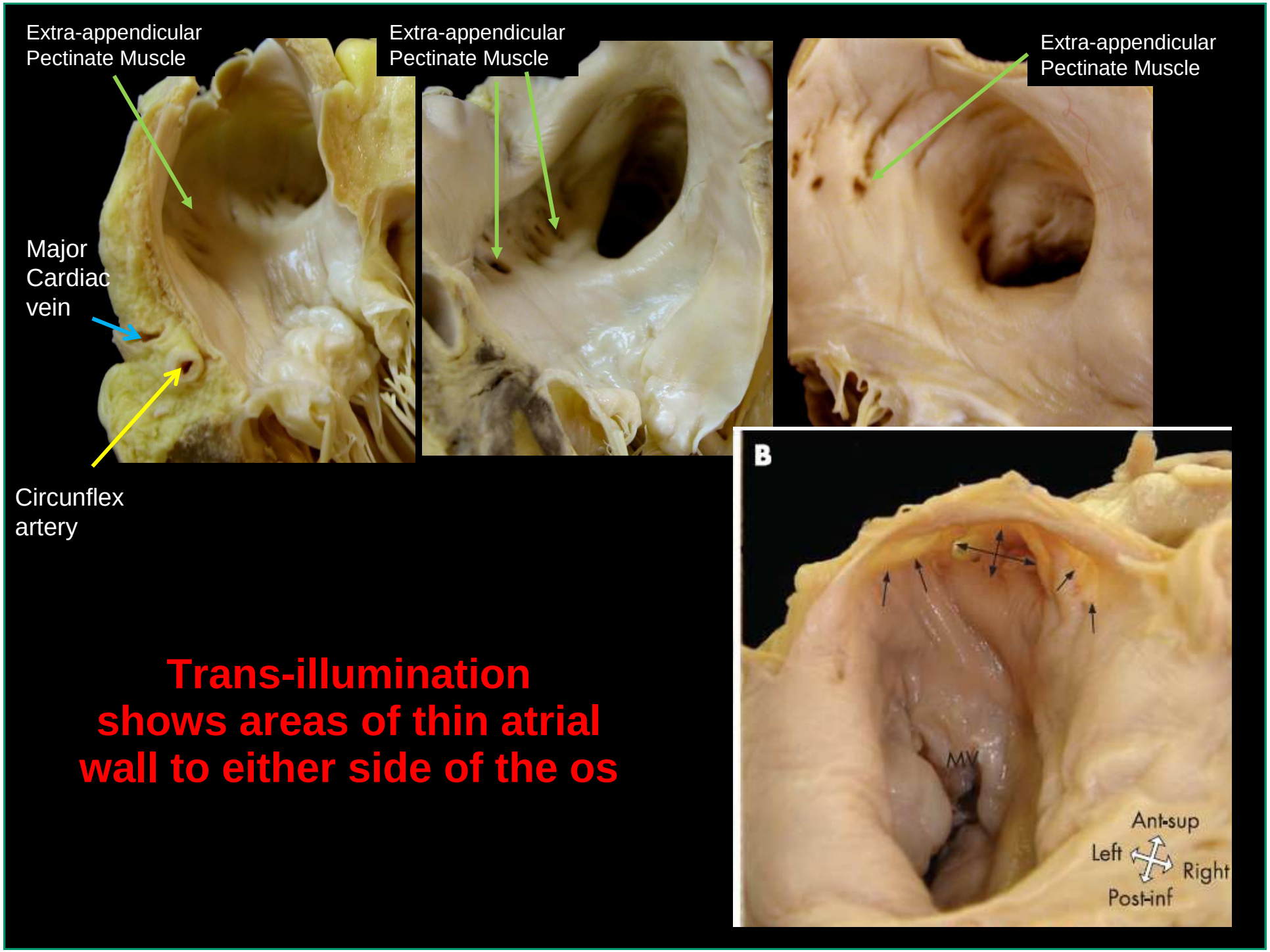
Il trattamento mediante chiusura percutanea dell'auricola sinistra è indicato se coesistono le seguenti condizioni cliniche:

FA cronica persistente o parossistica, da almeno 3 mesi

Alto rischio trombo embolico (CHA2DS2VaSc >=3)

Controindicazioni alla TAO assolute (diatesi emorragica, emorragia cerebralei, ulcera peptica attiva, sanguinamento recente gastrointestinale/genitourinario/respiratorio, severa insufficienza epatica o renale, ipertensione severa, allergia alla TAO, demenza, alcolismo, disturbi psichiatrici)



Trans-illumination shows areas of thin atrial wall to either side of the os

Historically

Surgical Options

Madden carried out the first LAA surgical excision in humans in 1949

Excision of the LAA

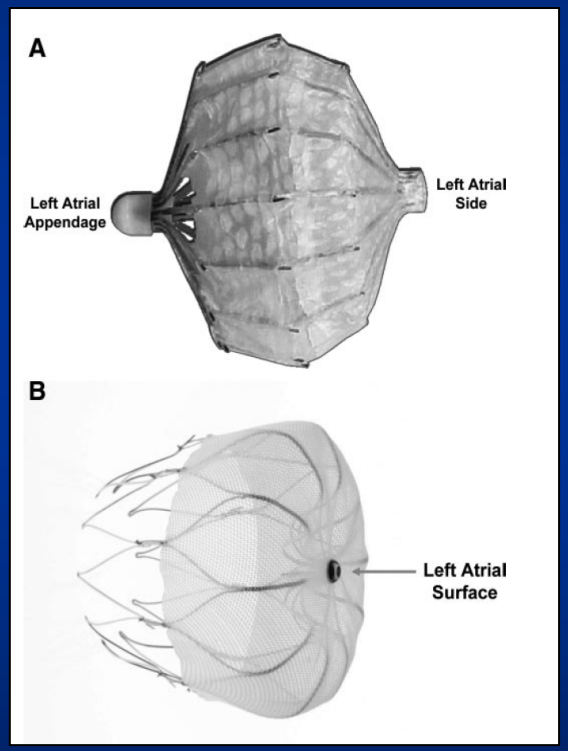
Suture ligation of LAA

Percutaneous Management

New techniques have emerged which have enabled this process to be done percutaneously without exposing patients to high-risk invasive surgery

Percutaneous **DEVICE USED**

Ball shaped

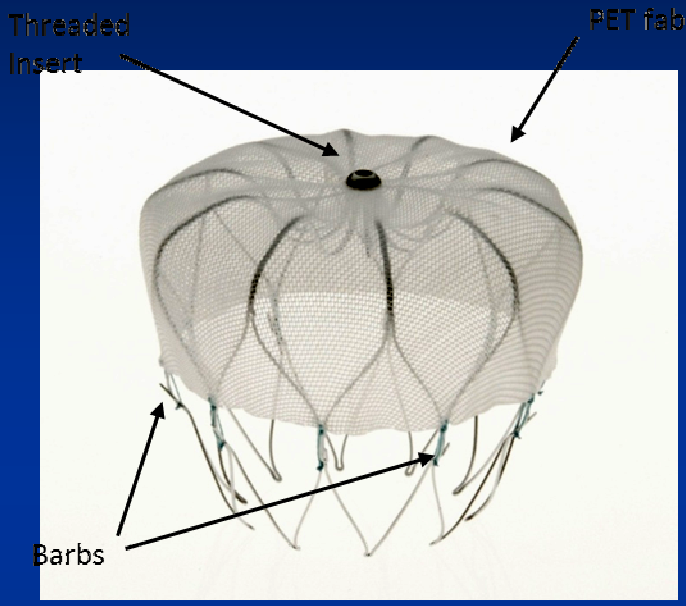


Jellyfish shaped

The LARIAT suture delivery system

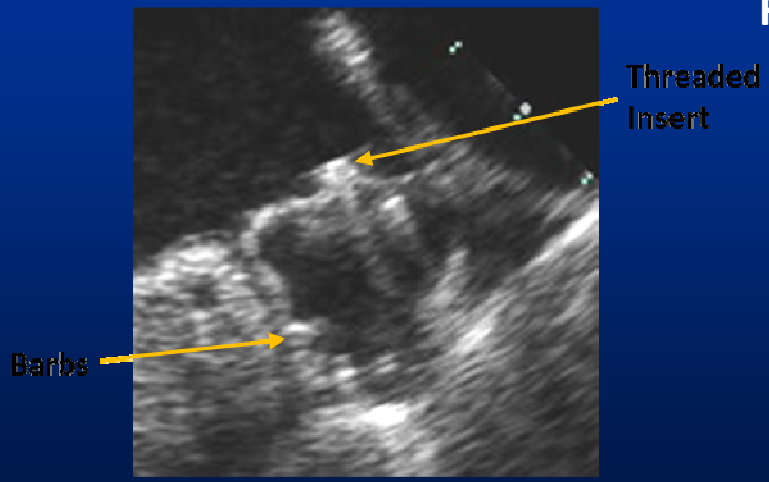
Disc + lobe

Sistema Watchman



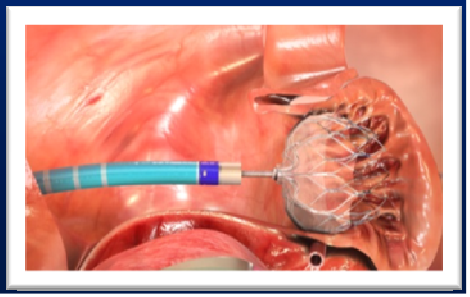
Struttura: Nitinolo

- Autoespandibile
- Misure disponibili: 21, 24, 27, 30, 33 mm (diametro)
- 10 barbe di fissaggio intorno al dispositivo per l'ancoraggio al tessuto cardiaco
- Profilo progettato per adattarsi alla maggior parte delle anatomie

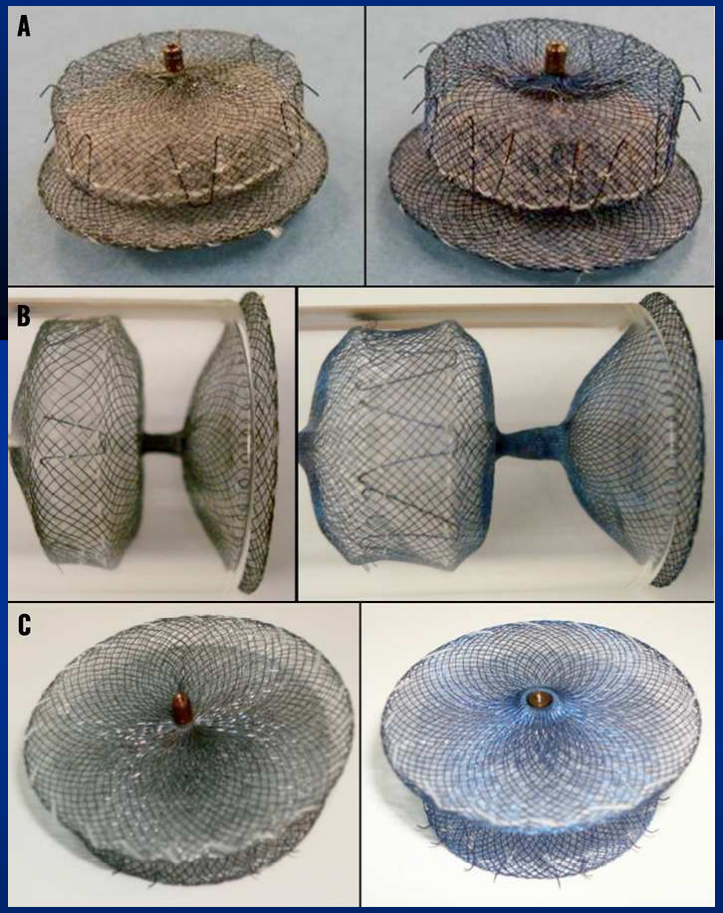


Filtro: (PET) Polietilentereftalato

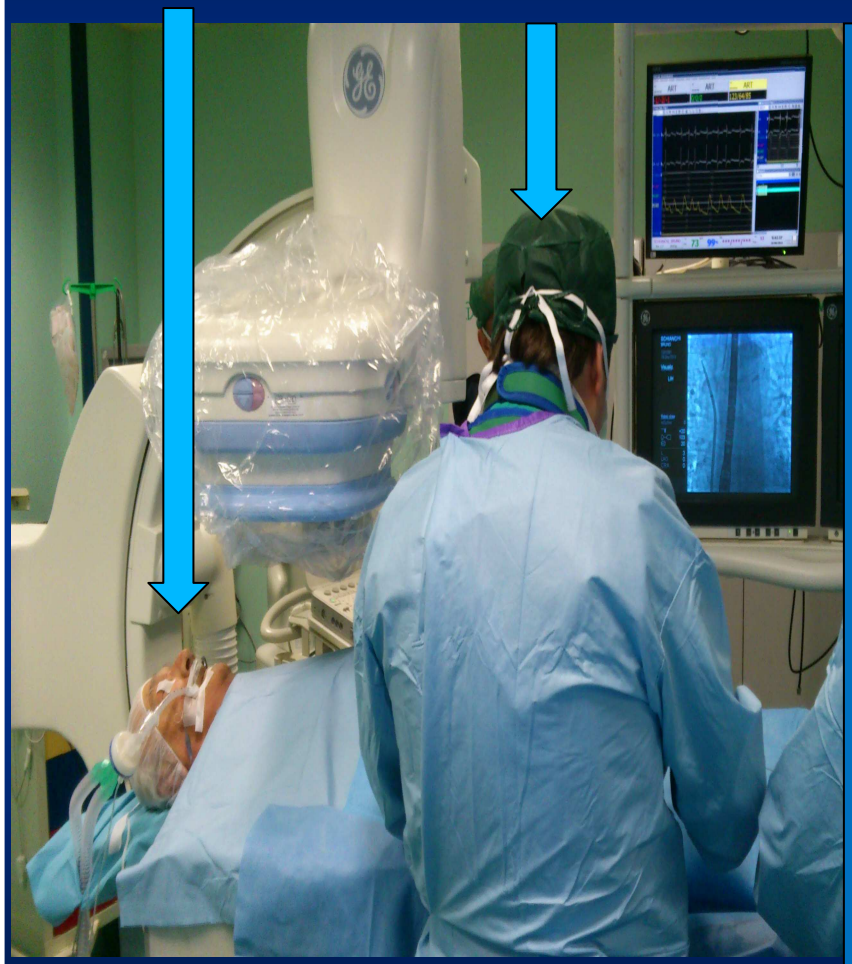
- 160 μ
- Membrana concepita per bloccare la fuoriuscita di trombi e favorire il processo di endotelizzazione

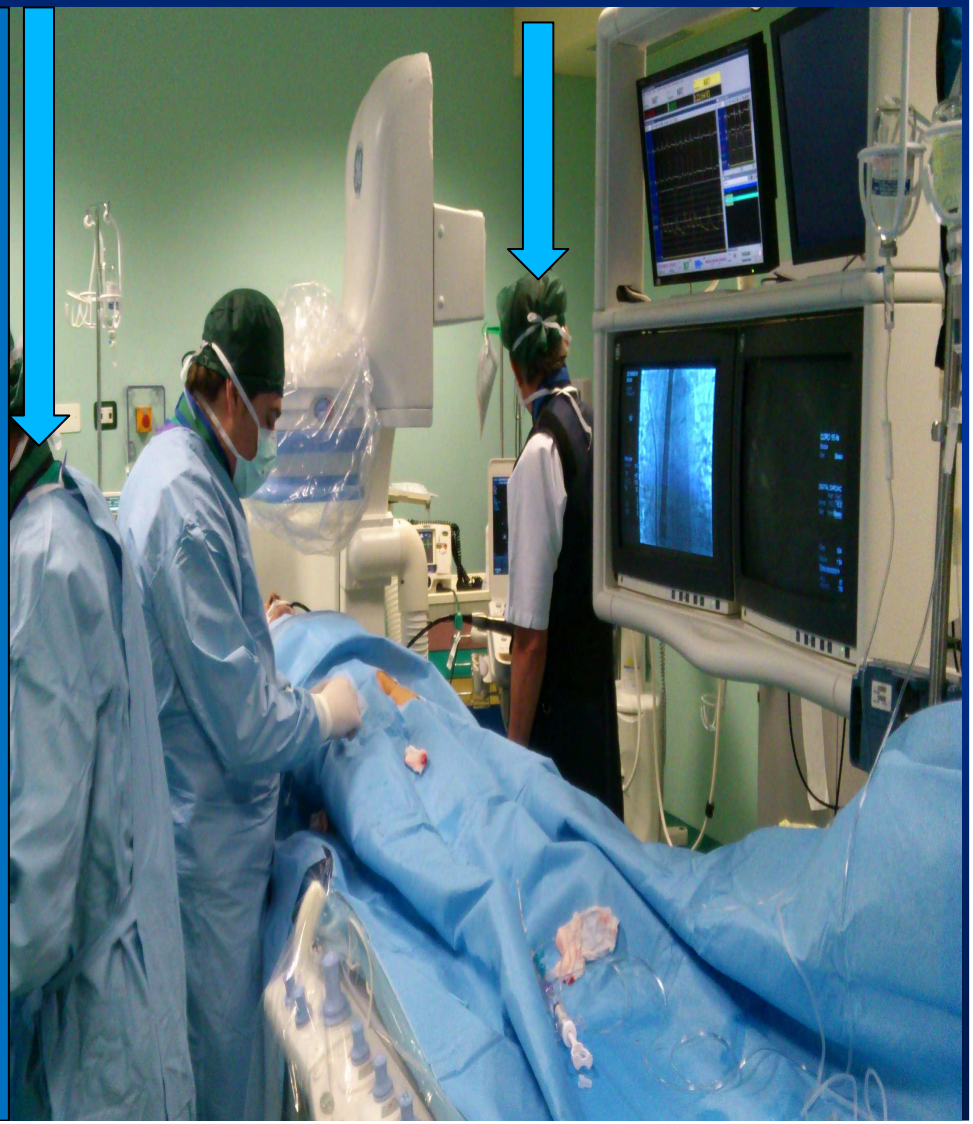


The Amplatzer™ Cardiac Plug 2 for left atrial appendage occlusion

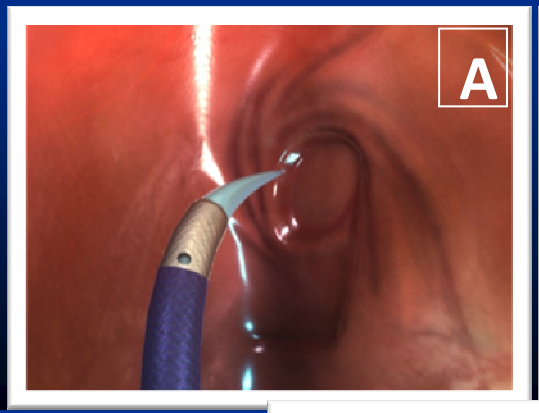


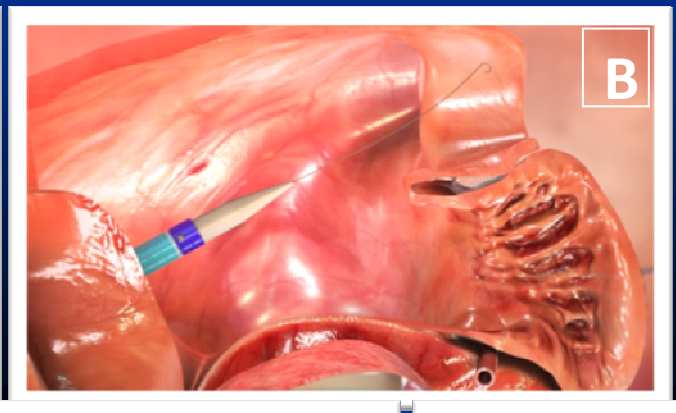
Cath-lab staff

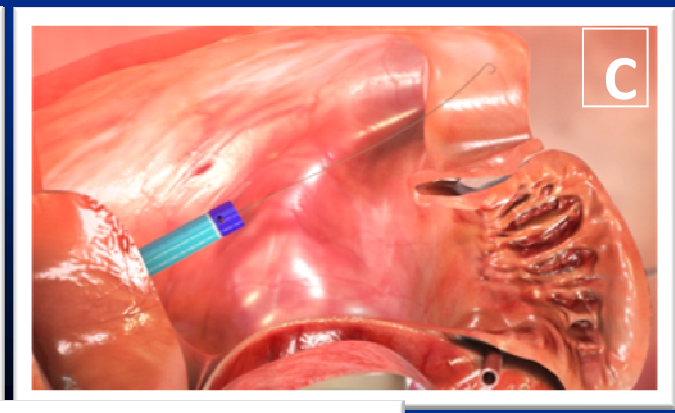


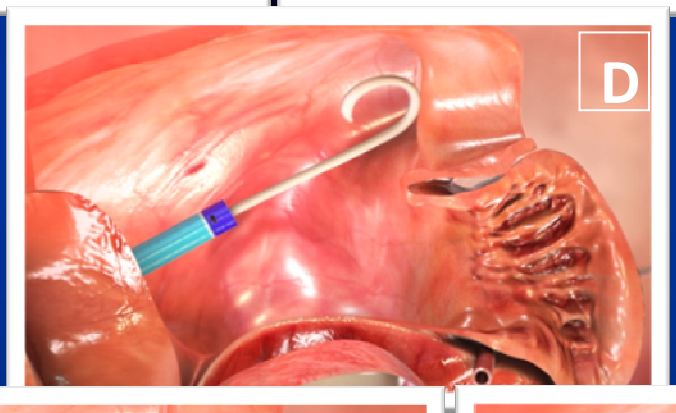


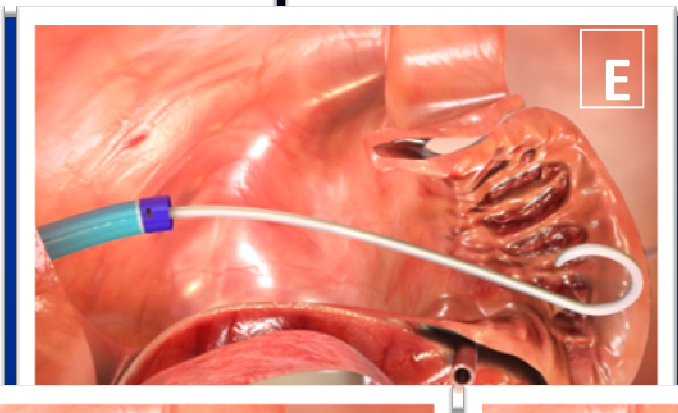
Procedura di impianto : principali step

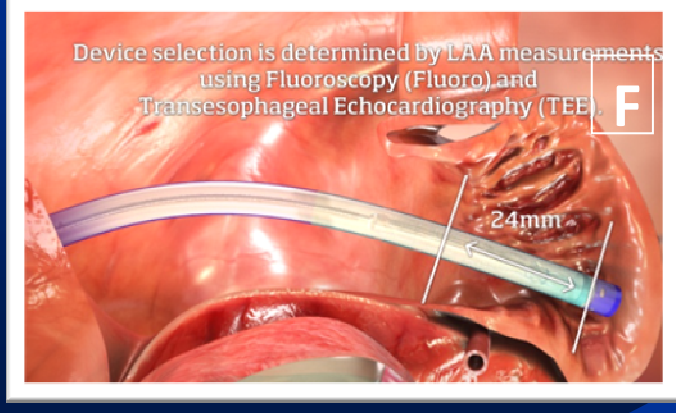


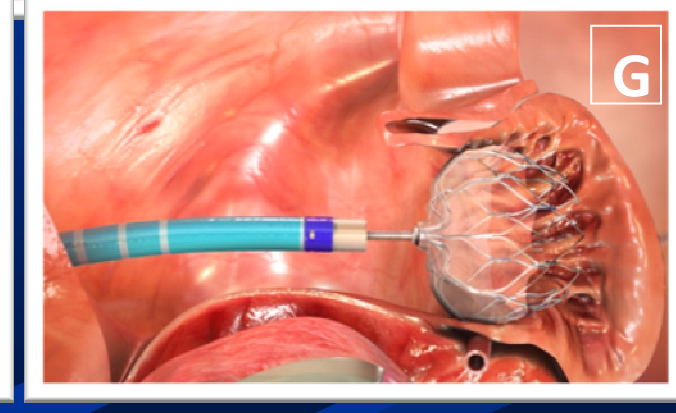


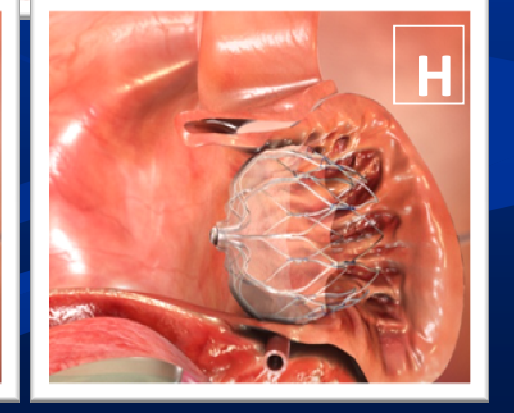












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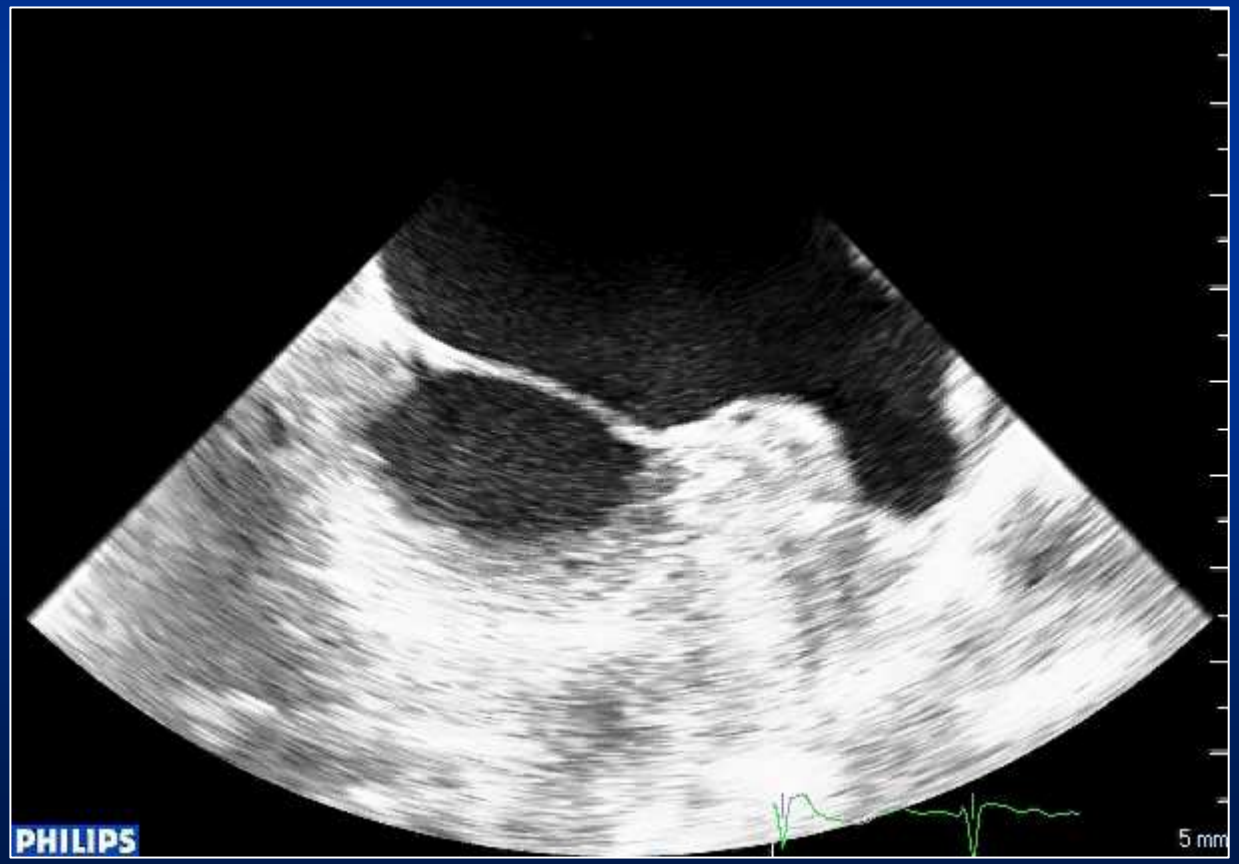
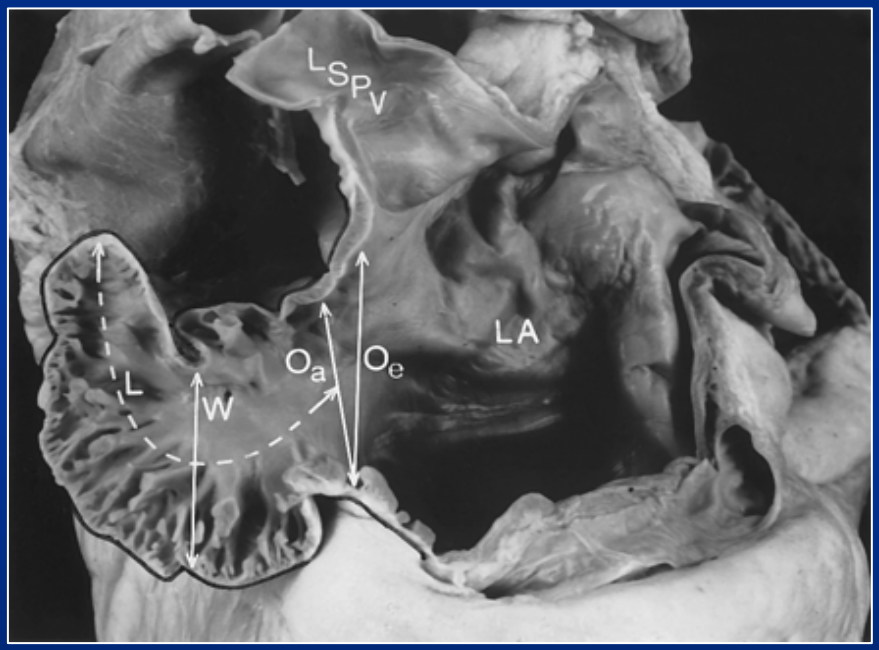
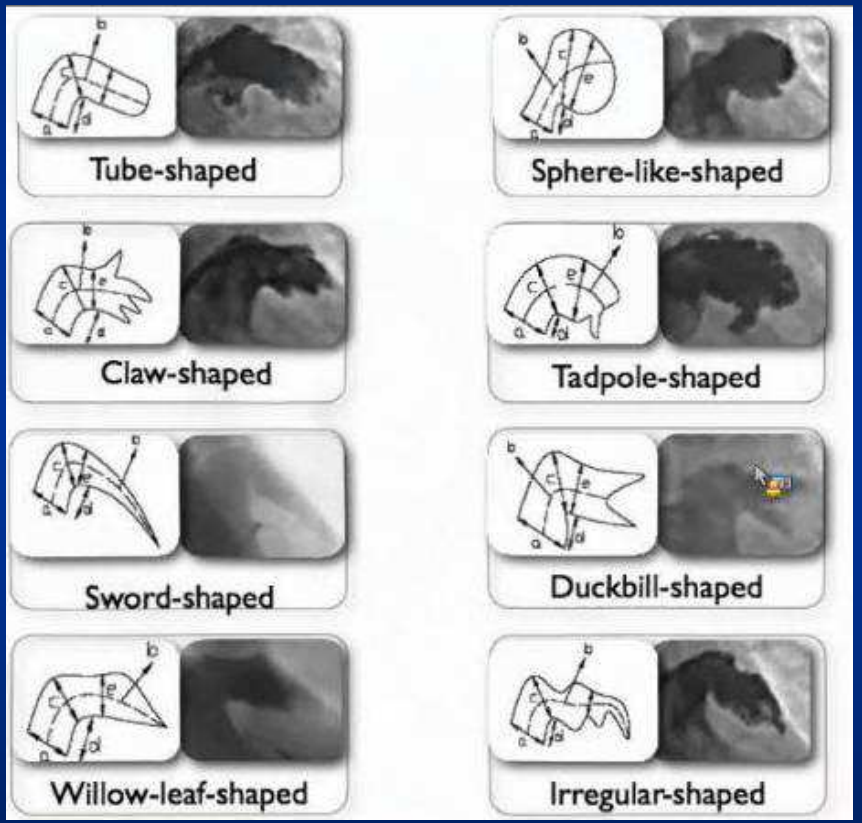
Pre-Procedural Trans-Esophageal Echocardiography (TEE)

Shape and diameter of Ostium
Deepness of LAA
Shape and dimension of landing zone



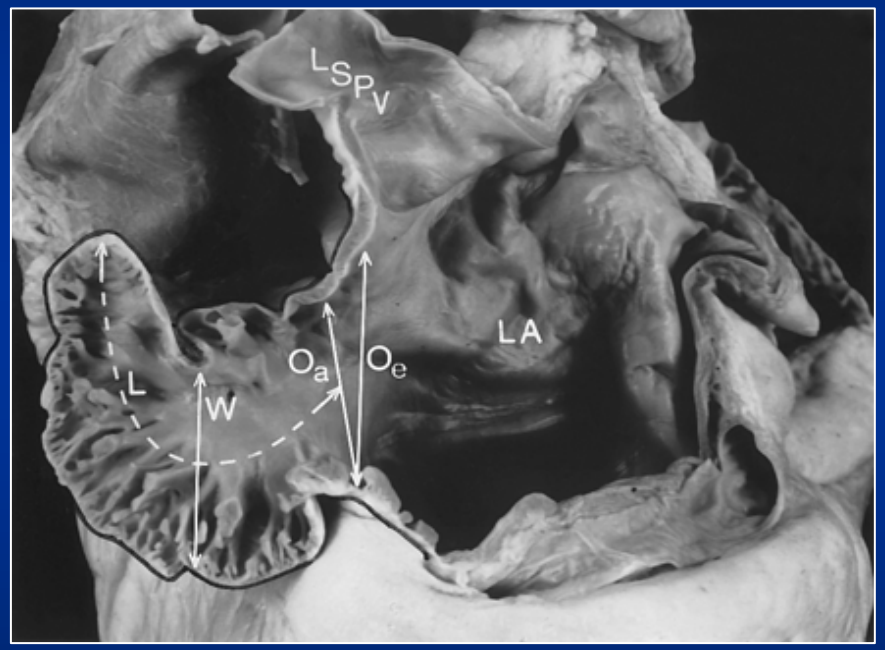
Anatomy of the Normal Left Atrial Appendage

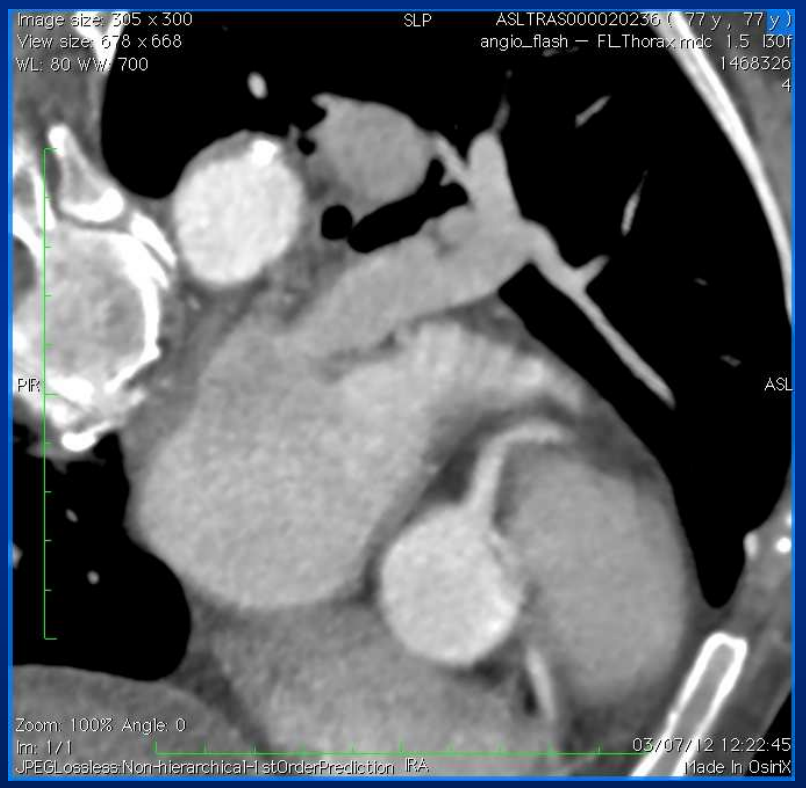




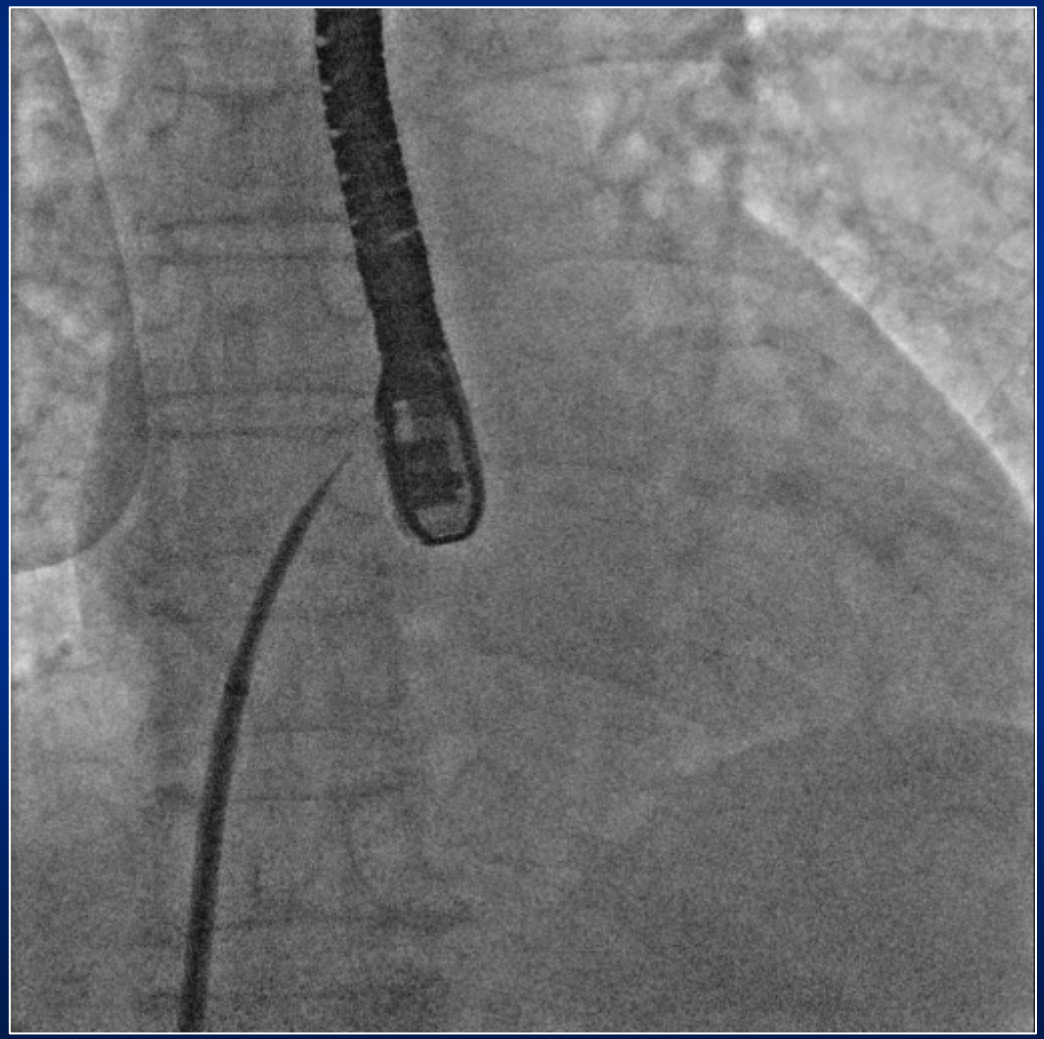
Anatomy of the Normal Left Atrial Appendage
A Quantitative Study of Age-Related Changes in 500 Autopsy Hearts: Implications for Echocardiographic Examination
John P. Veinot, MD; Phillip J. Harrity, MD; Federico Gentile, MD; Bijoy K. Khandheria, MBBS; Kent R. Bailey, PhD; Jeffrey T. Eickholt, BS; James B. Seward, MD; A. Jamil Tajik, MD; ; William D. Edwards, MD

Anatomy of the Normal Left Atrial Appendage





Trans-septal puncture



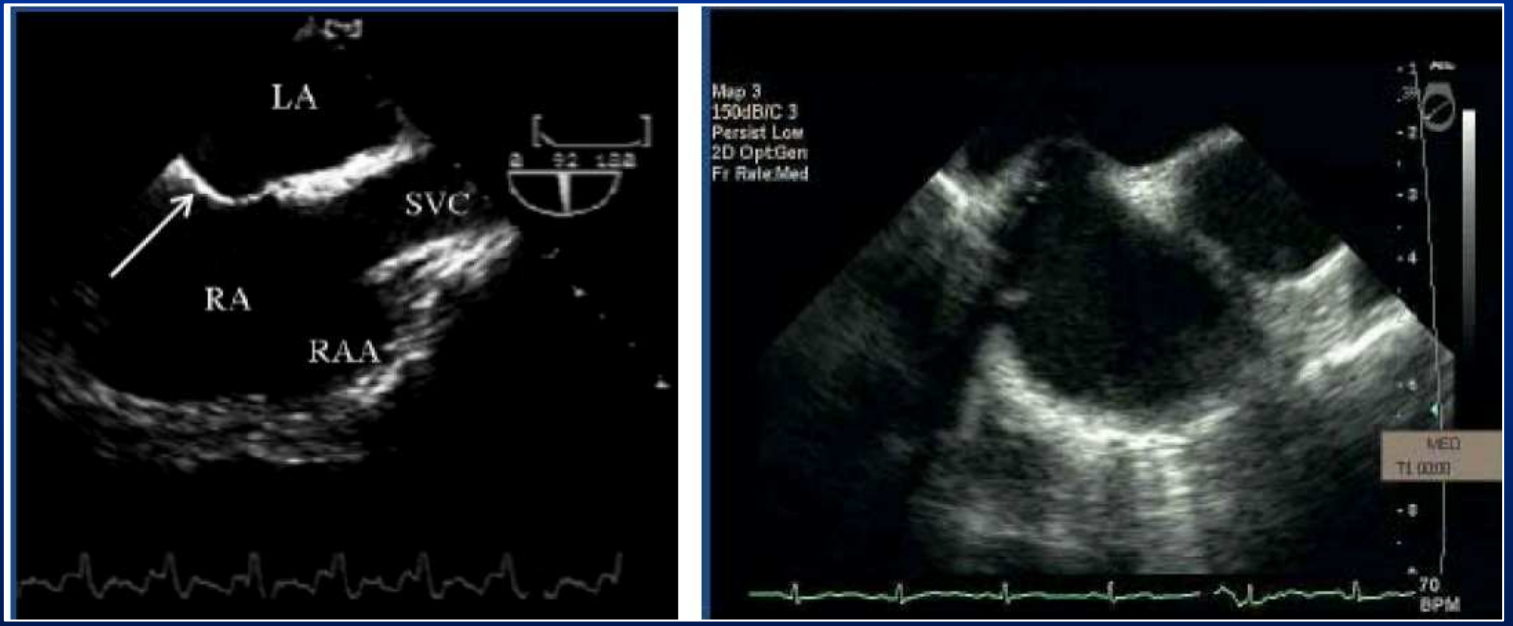
Trans-septal puncture

Fluoroscopy and echo are essential:

FLUOROSCOPY: AP view RAO 20° + LAO 90°

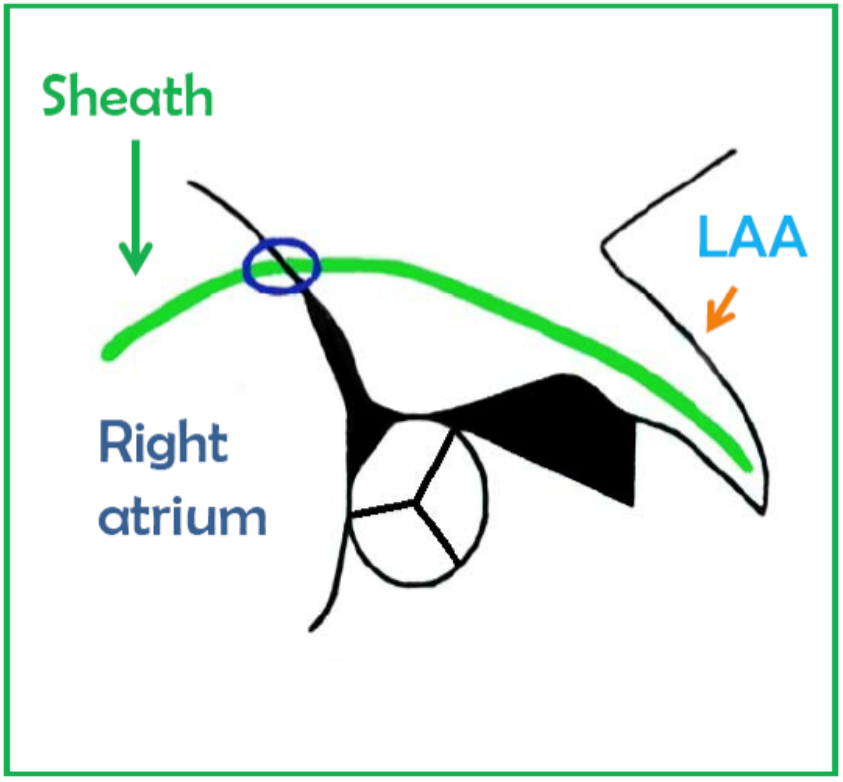
TEE:Bicaval view(80° 110° : height)

Short axis view (30° - 60° : mid)

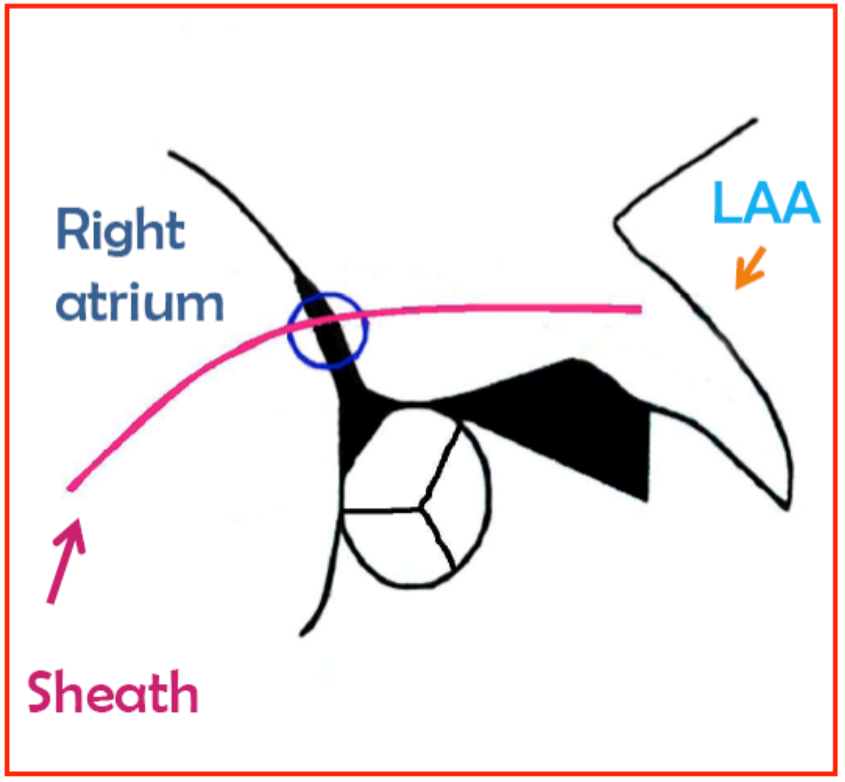


Trans-septal puncture

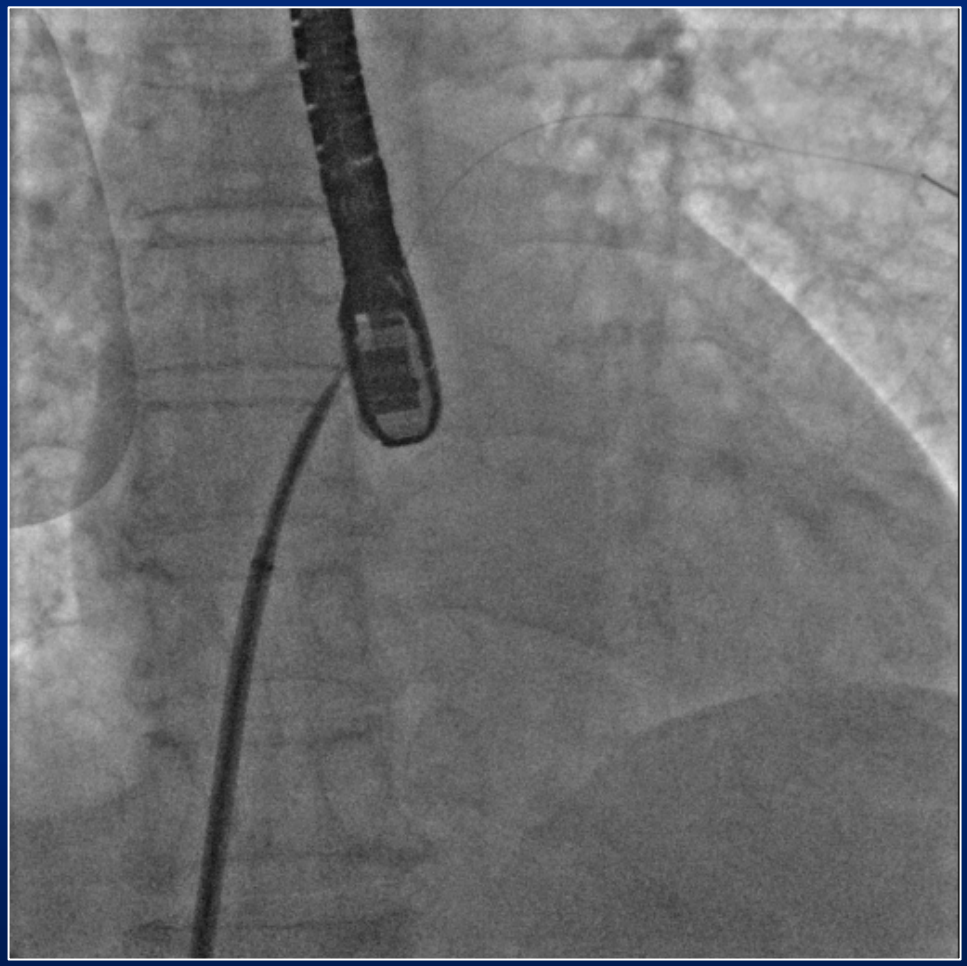
Sheath through inf-post septum
(correct site of puncture)

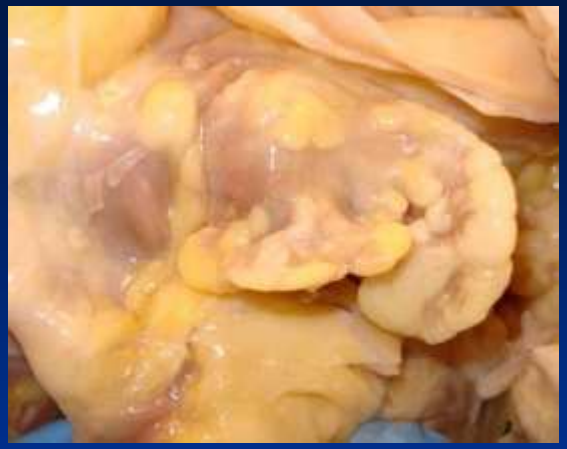


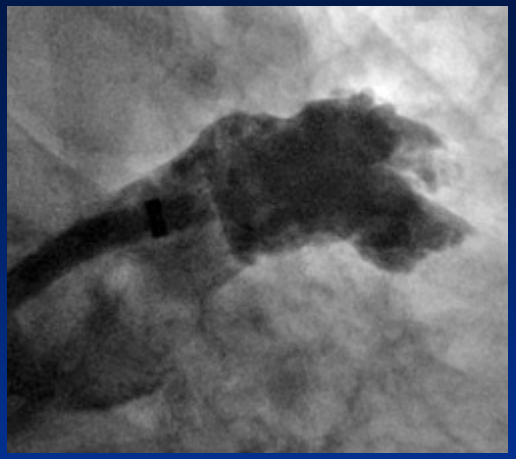
Sheath through PFO
("uncomfortable" position)



Left atrium entrance







Multiple lobes of the LAA

Clinical Implication

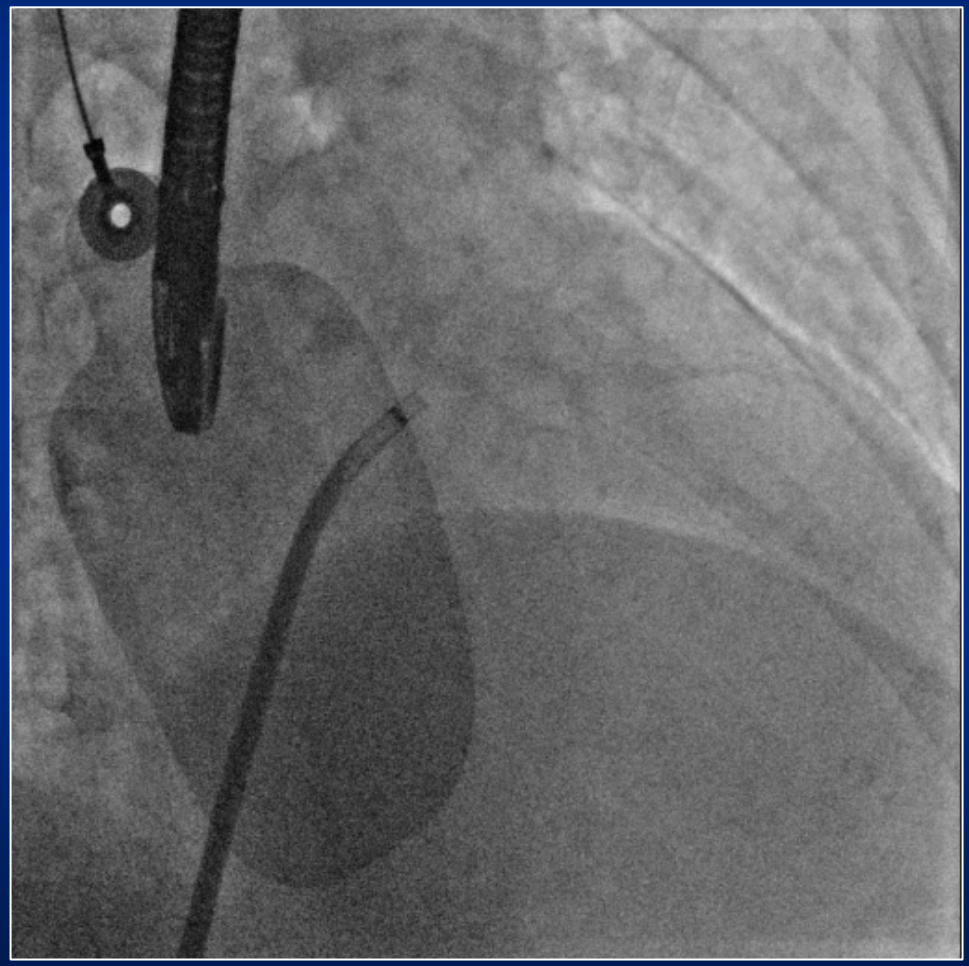
Multiple lobes are commonly seen and often located in the distal of the LAA

Thin walled LAA

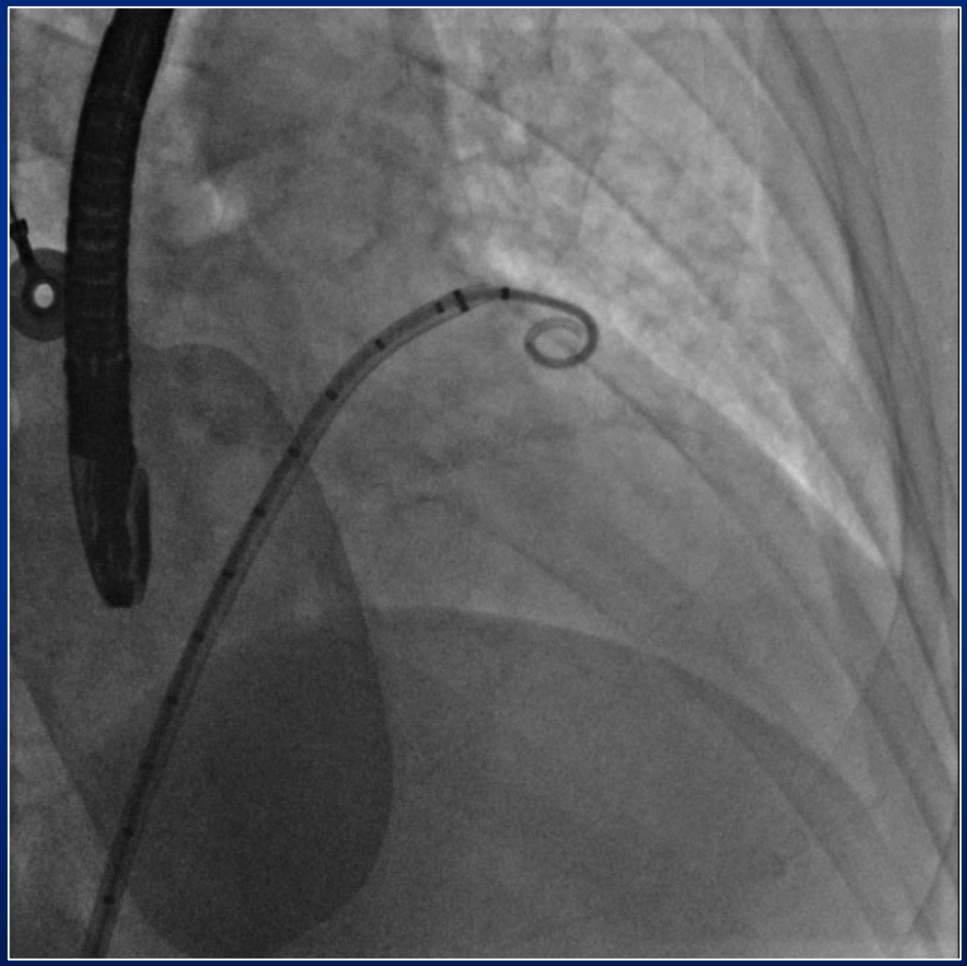
Handle with care

Avoid direct contact of the LAA wall with sheath, dilator, and endscrew of constrained device in a delivery sheath

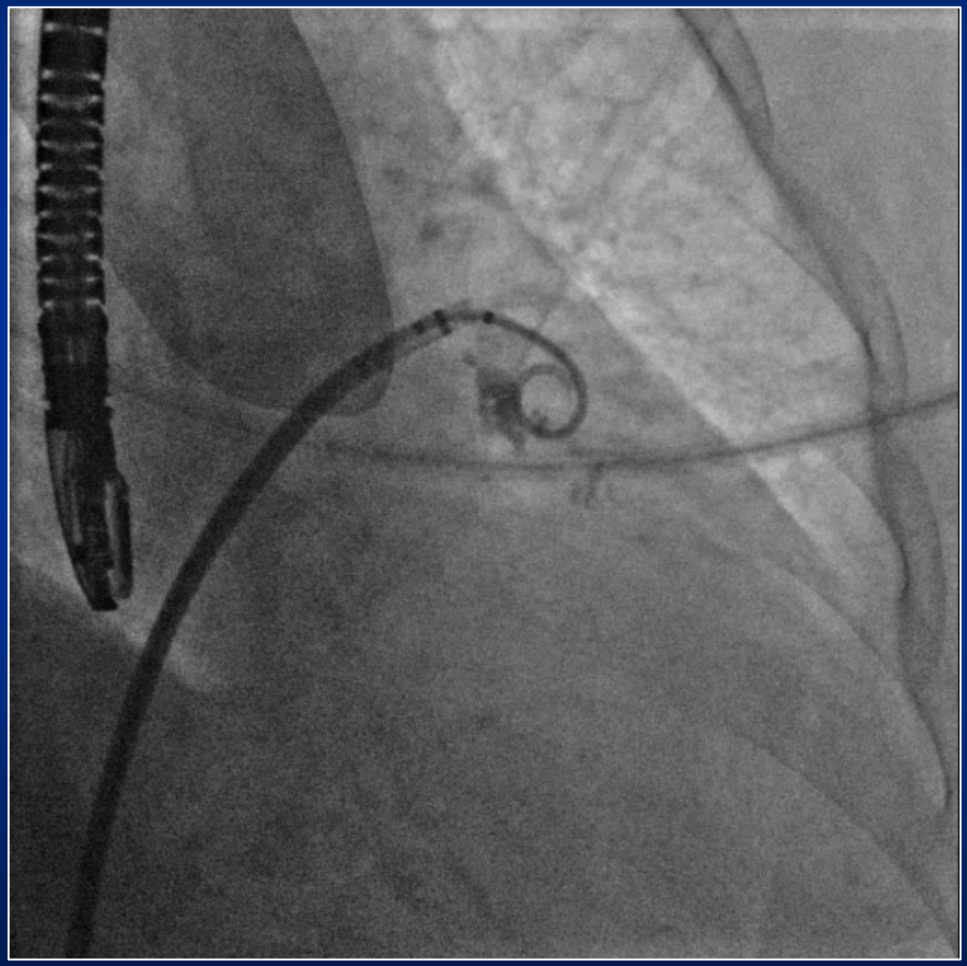
Angiography of left atrial appendage



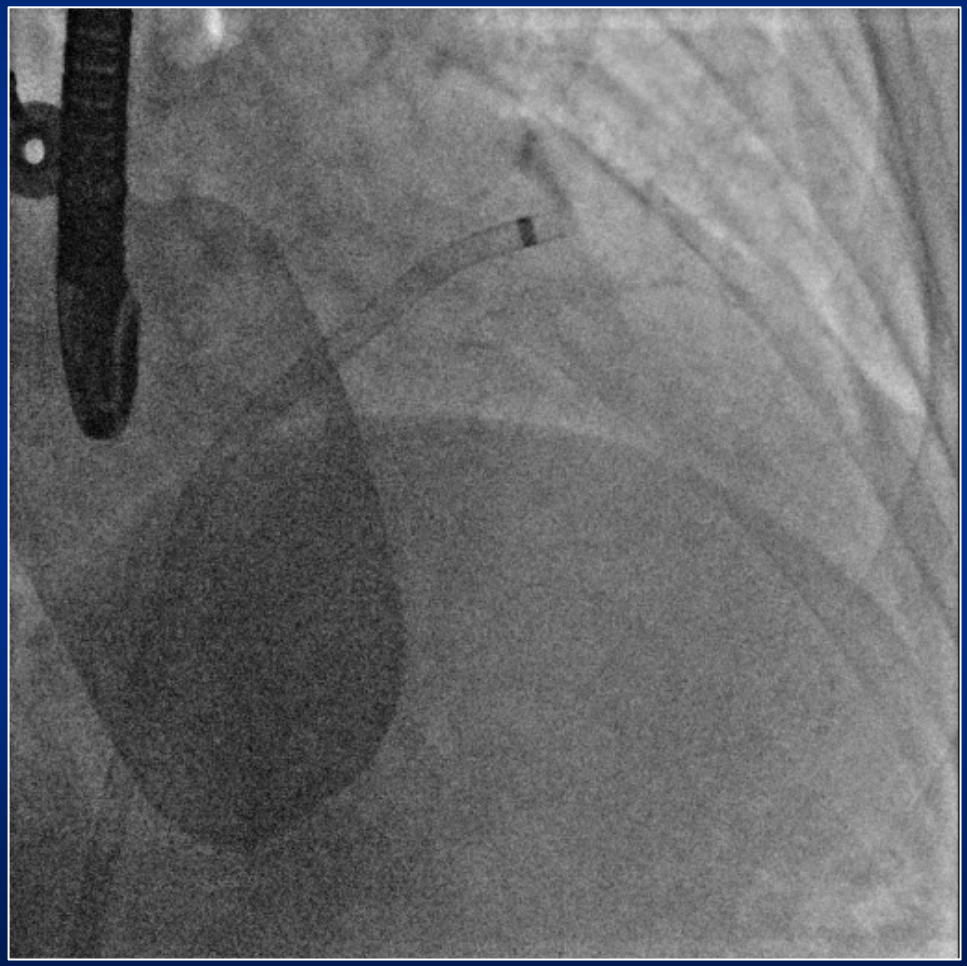
Pig Tail catheter advancement



Angiography



Sizing



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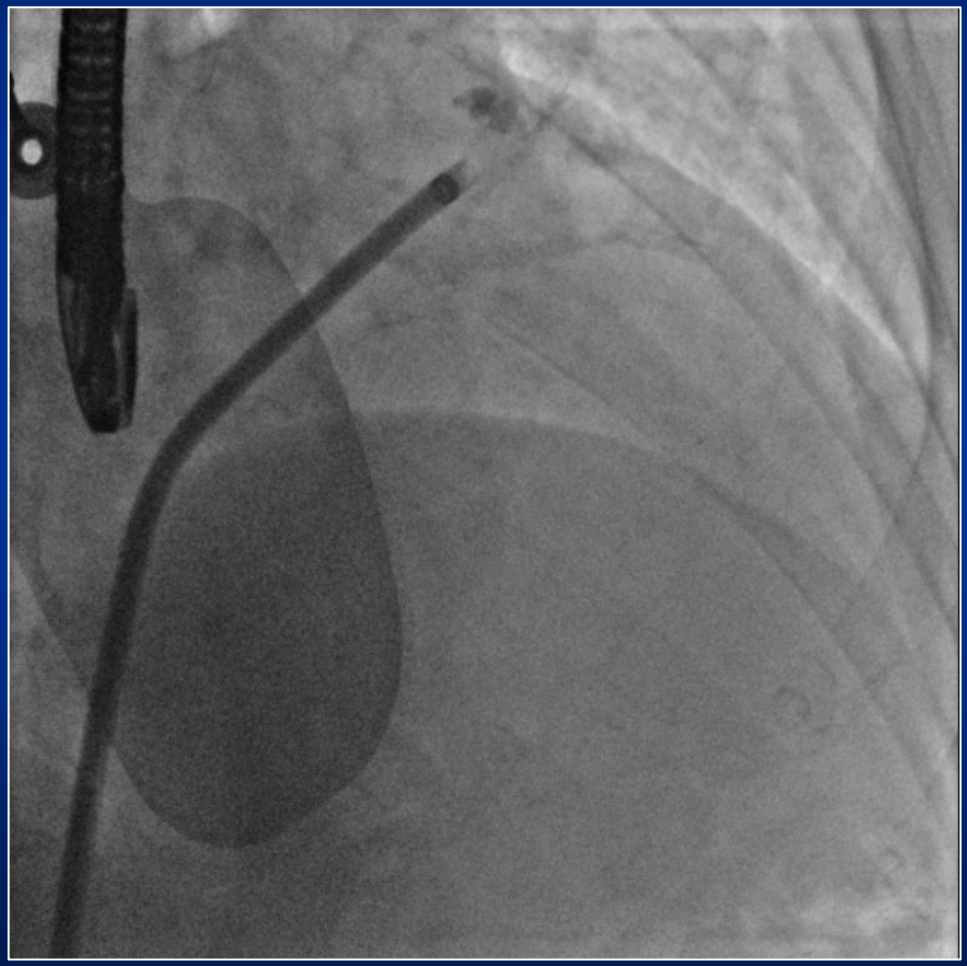

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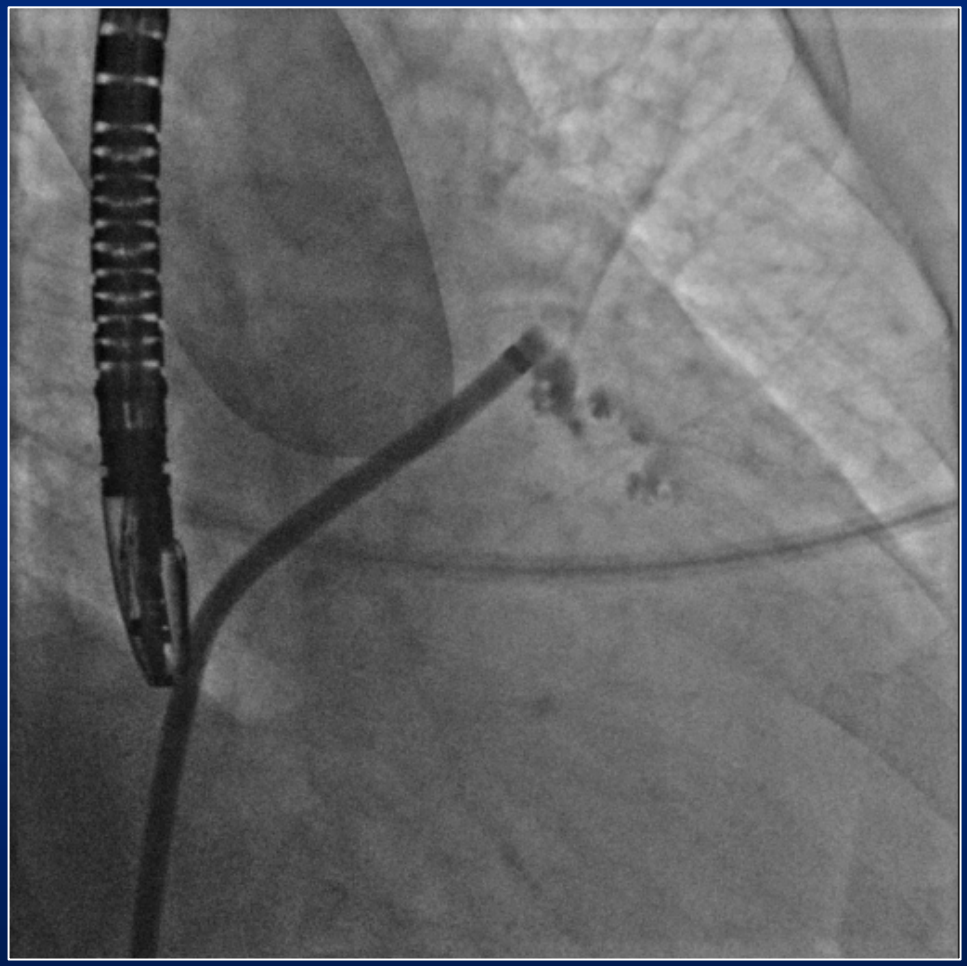
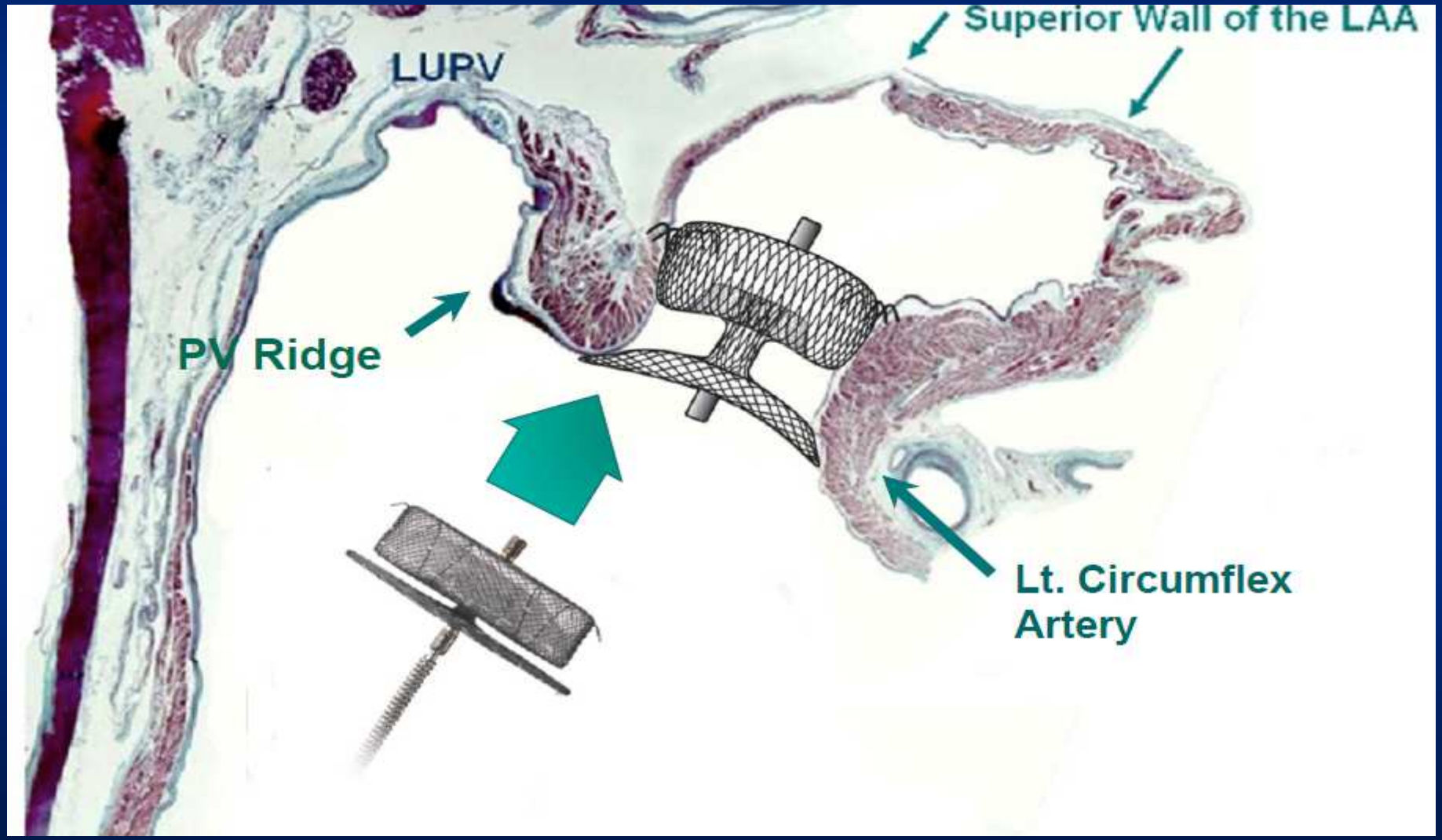


Device Sizing



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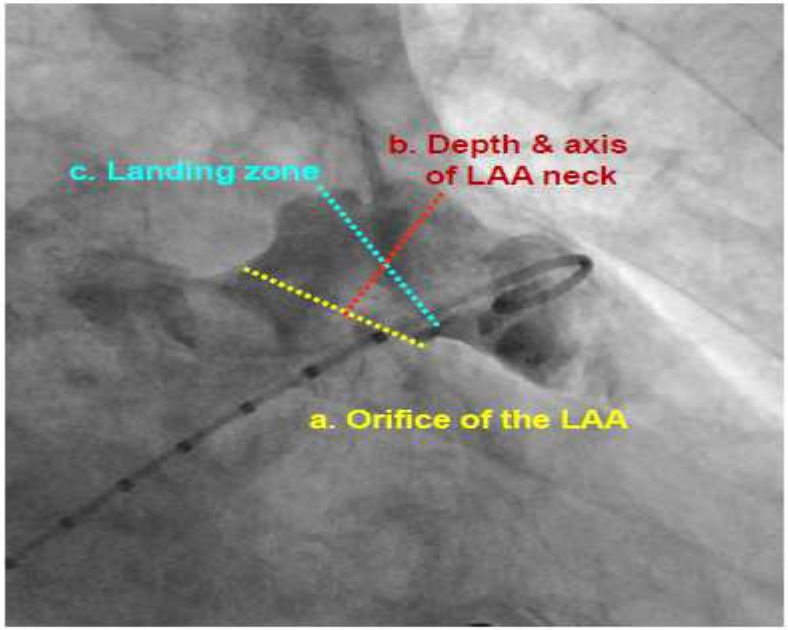
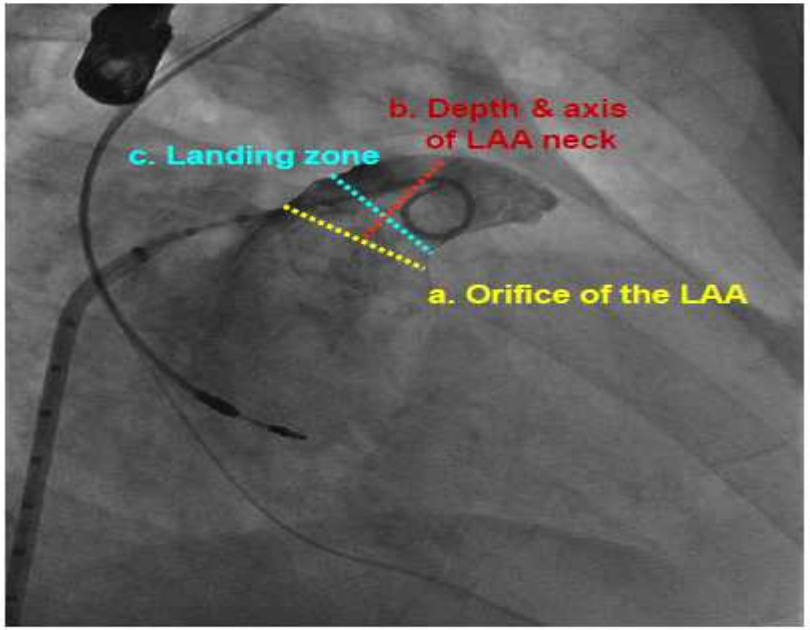
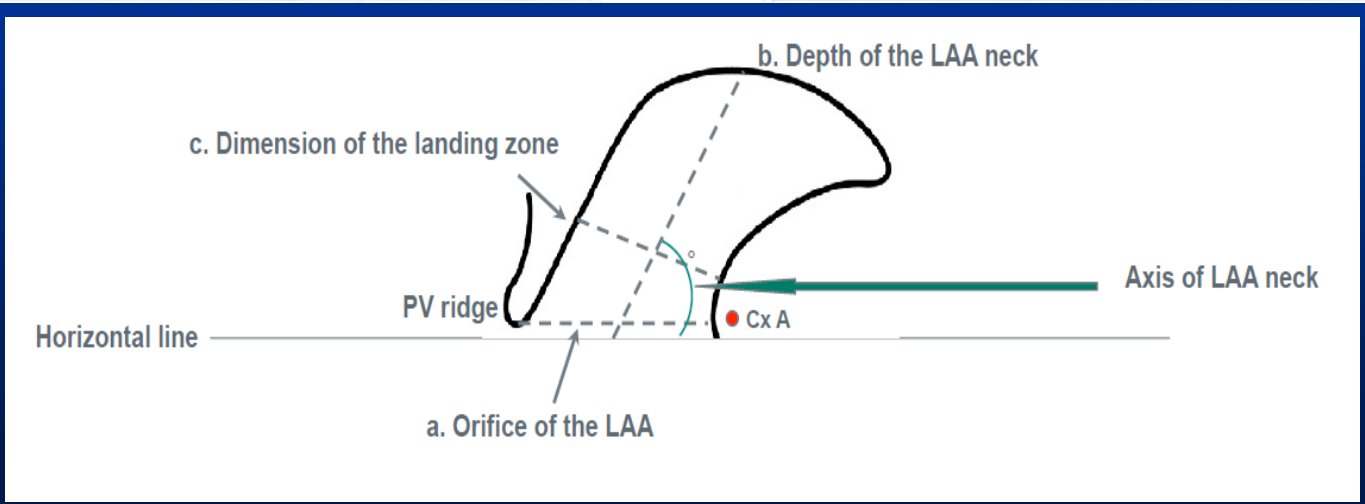


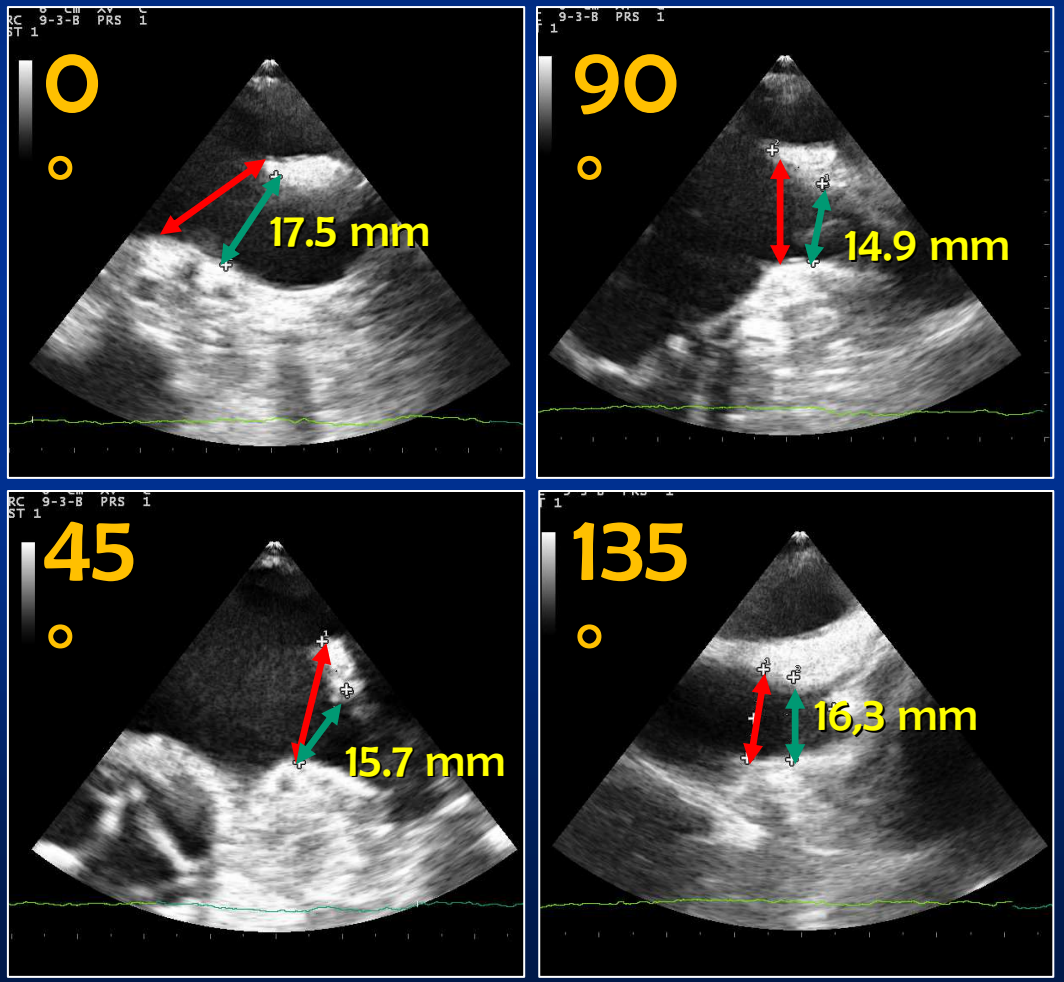




Device Sizing

Procedural TEE:

multiple view of LAA taken measurements for the ACP



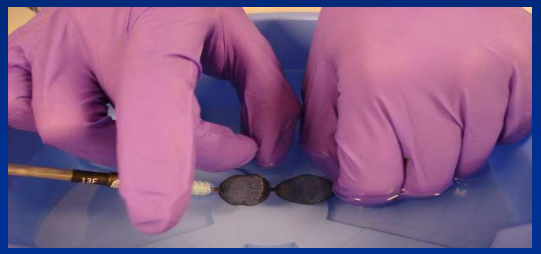
0° and 135° often show largest ostium diameter

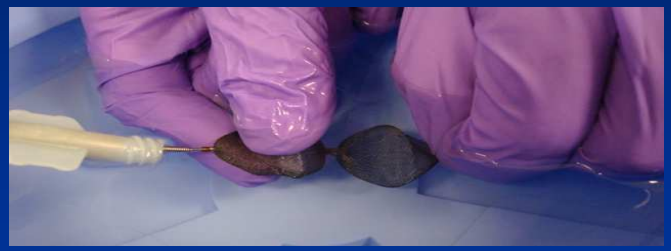
ostium of LAA

landing zone

Size of ACP needs to be up to 4 mm > max landing zone diameter.

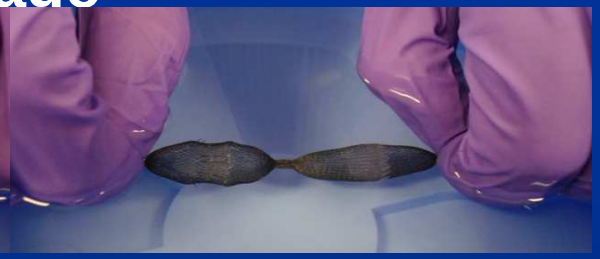
AVOID ISCHAEMIC STROKE



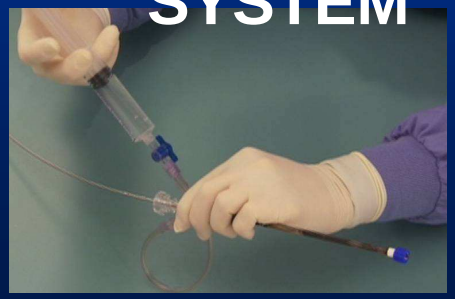


Flick with fingers

Massage



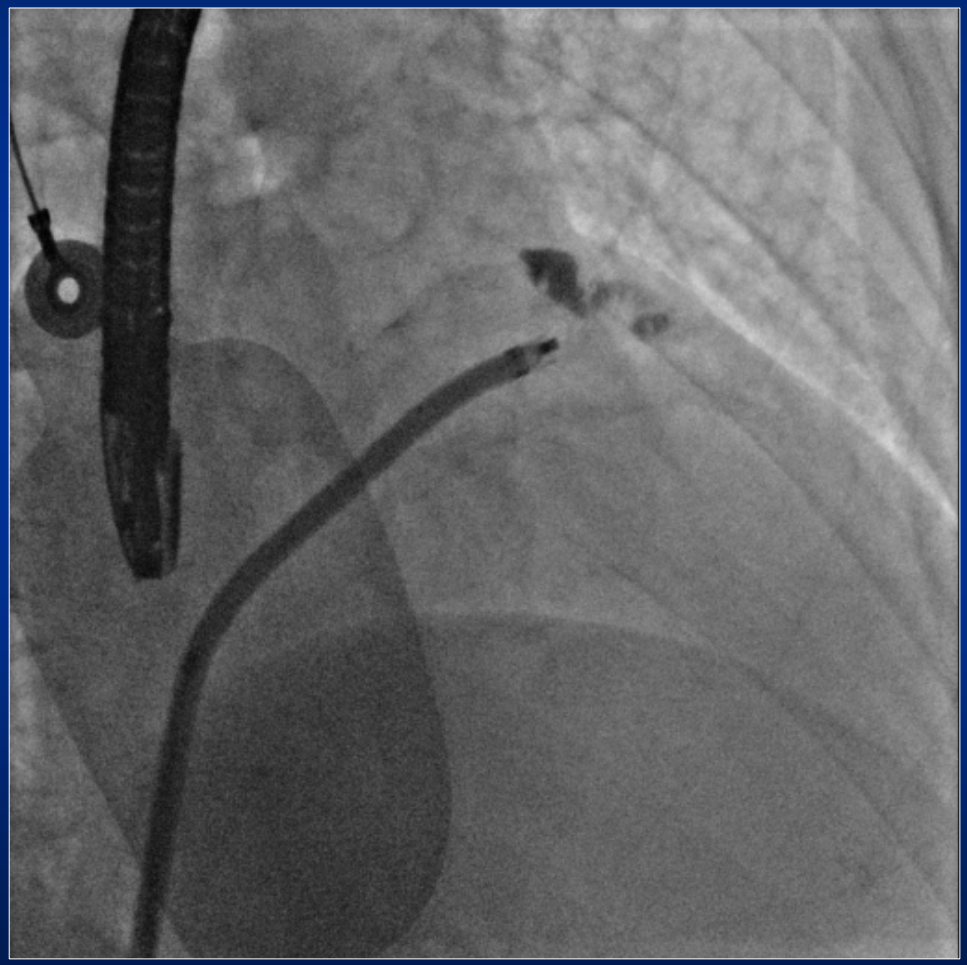
FLUSHING THE SYSTEM



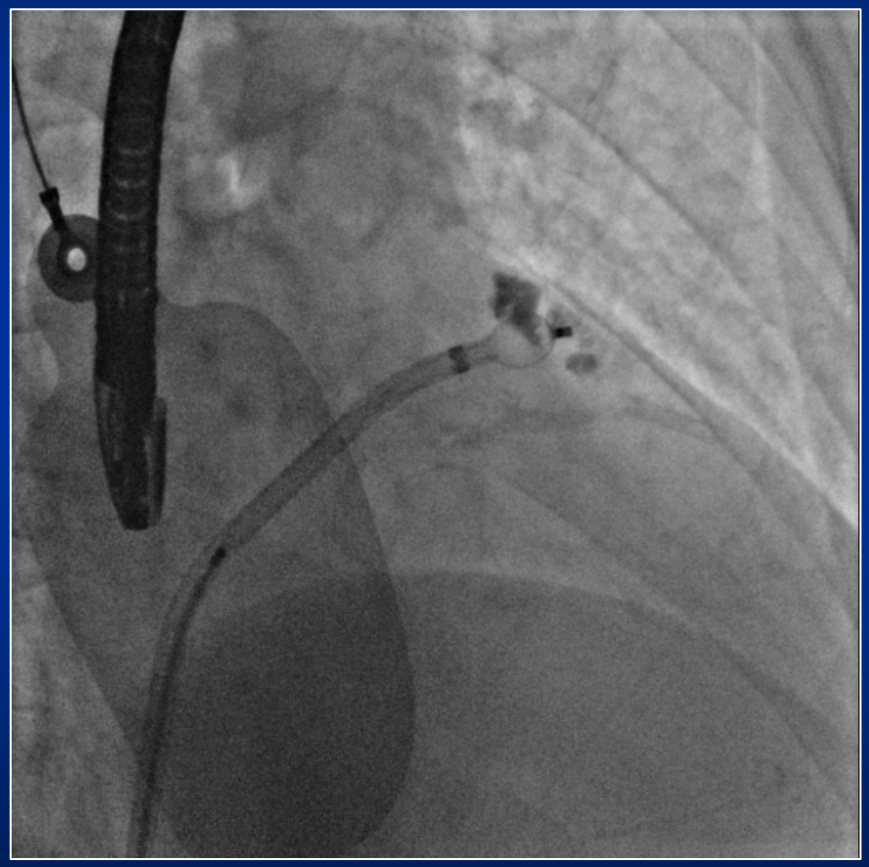
Stretch the device repeatedly

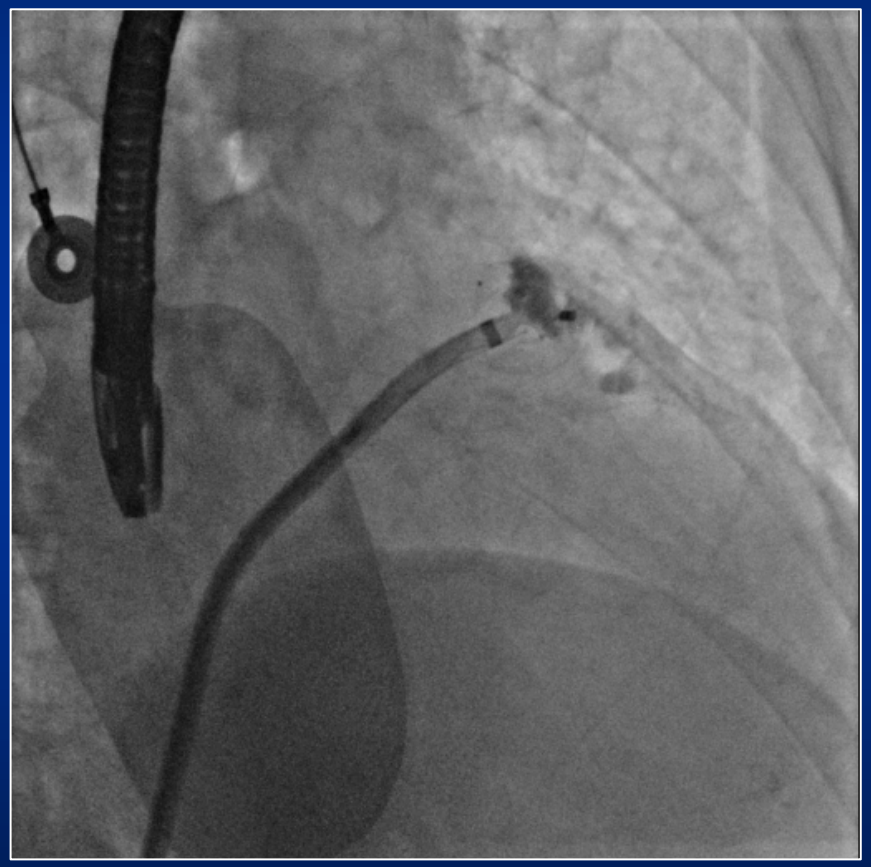
- **Advance the device slowly**
- **Keep sidearm on the Tuohy-Borst open to a saline filled syringe while advancing the device**
- **Purge potential air bubbles at the hub of the Tuohy-Borst out from the adapter valve before injecting contrast medium for angiography**

ACP advancement



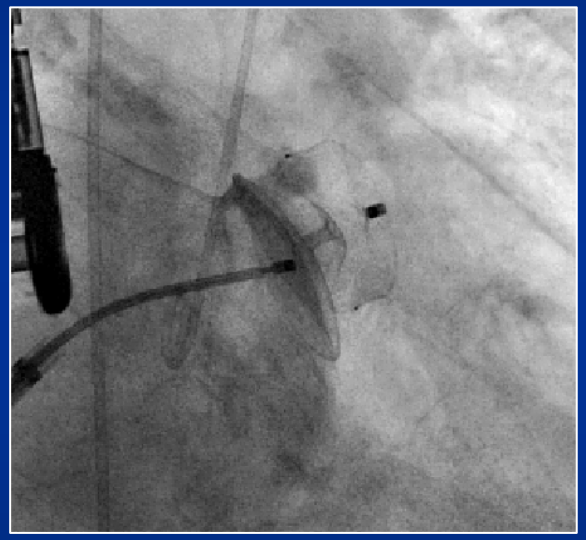
Lobe deployed





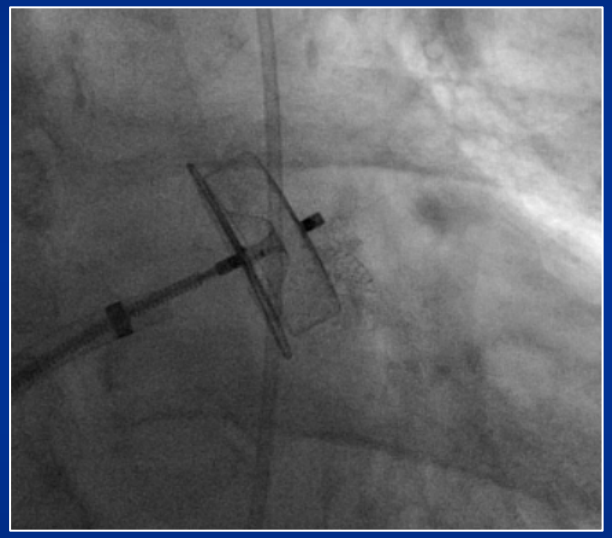
Lobe deployed

PROPER sized



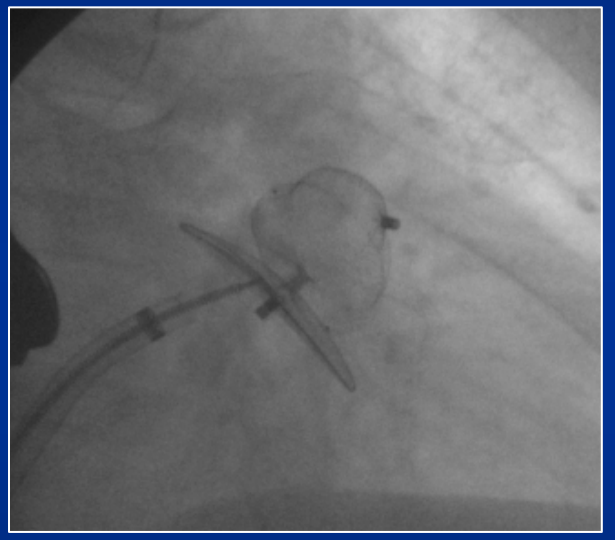
“Tire” shaped - Proper tension on the device by the LAA

UNDER sized



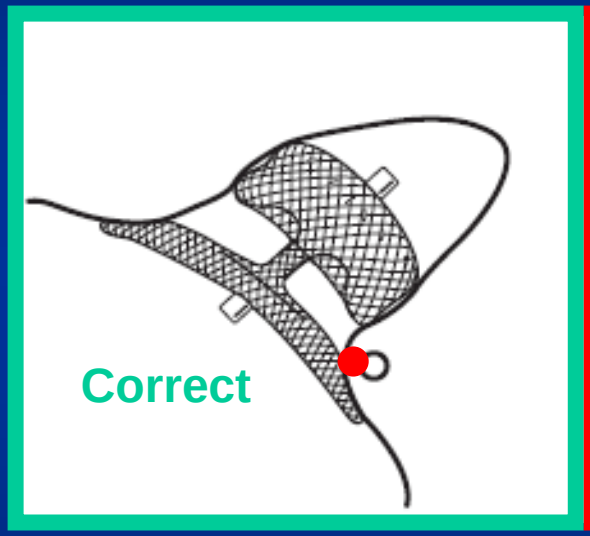
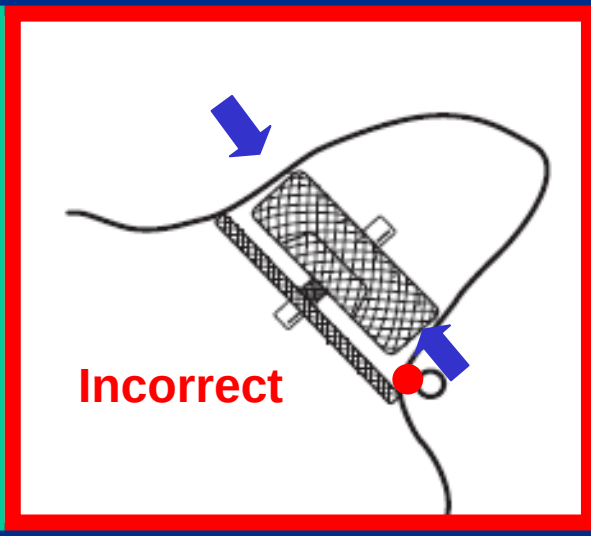
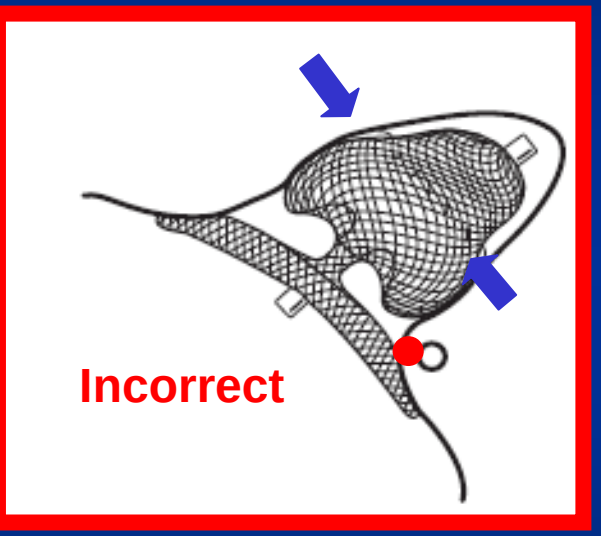
“Puck” shaped – No tension on the device from the LAA wall

OVER sized

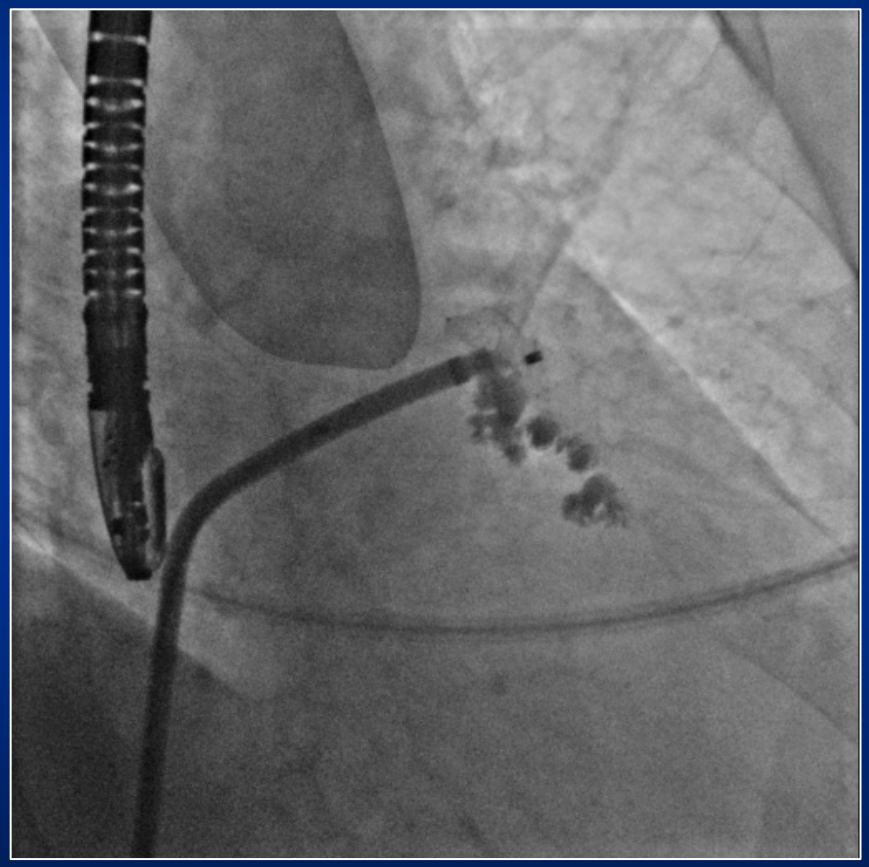


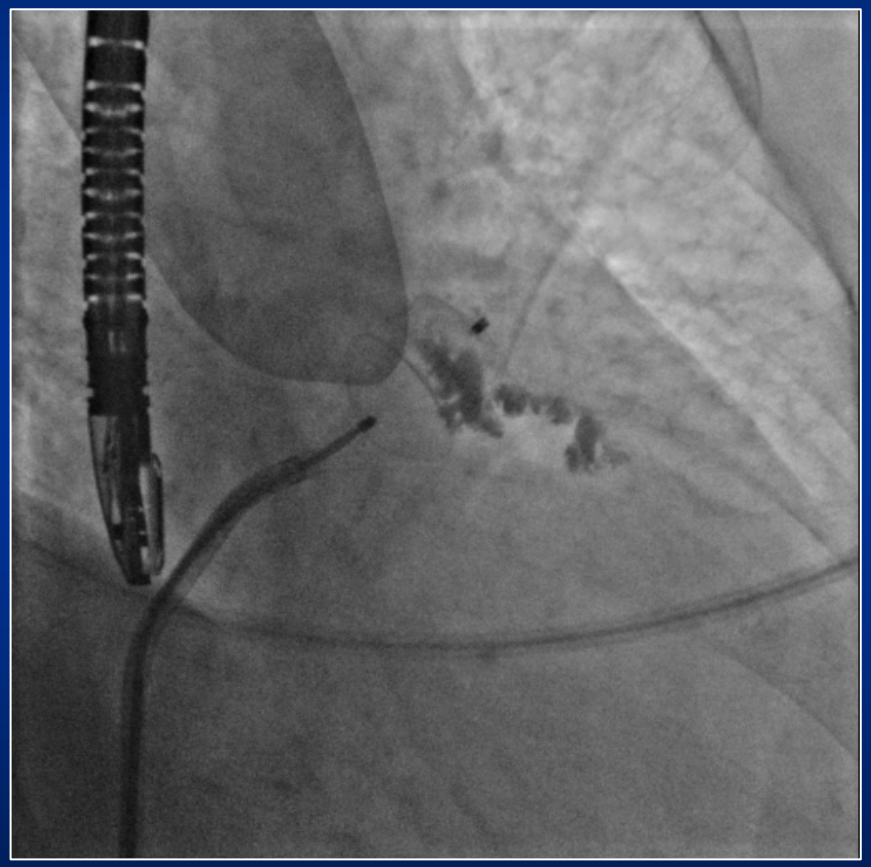
“Strawberry” shaped – the device is being squeezed

Lobe deployed

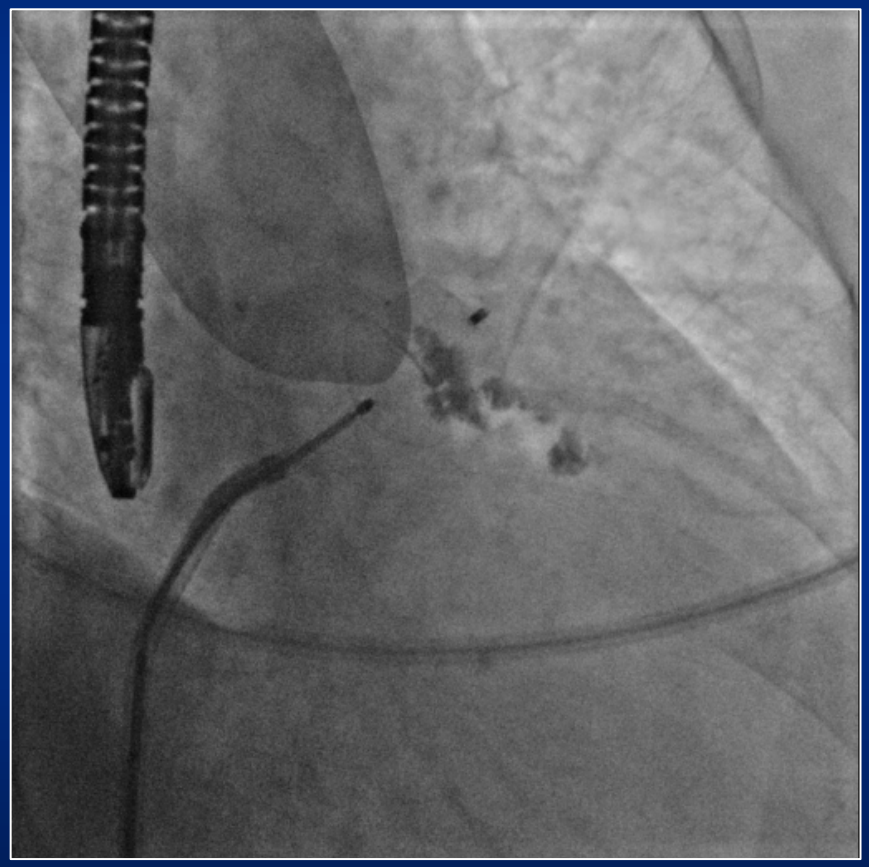
Tire shaped	Puck shaped	Strawberry shaped
		
Stable	**Unstable**	**Unstable**
Stabilizing wires engaged	**Stabilizing wires unengaged**	

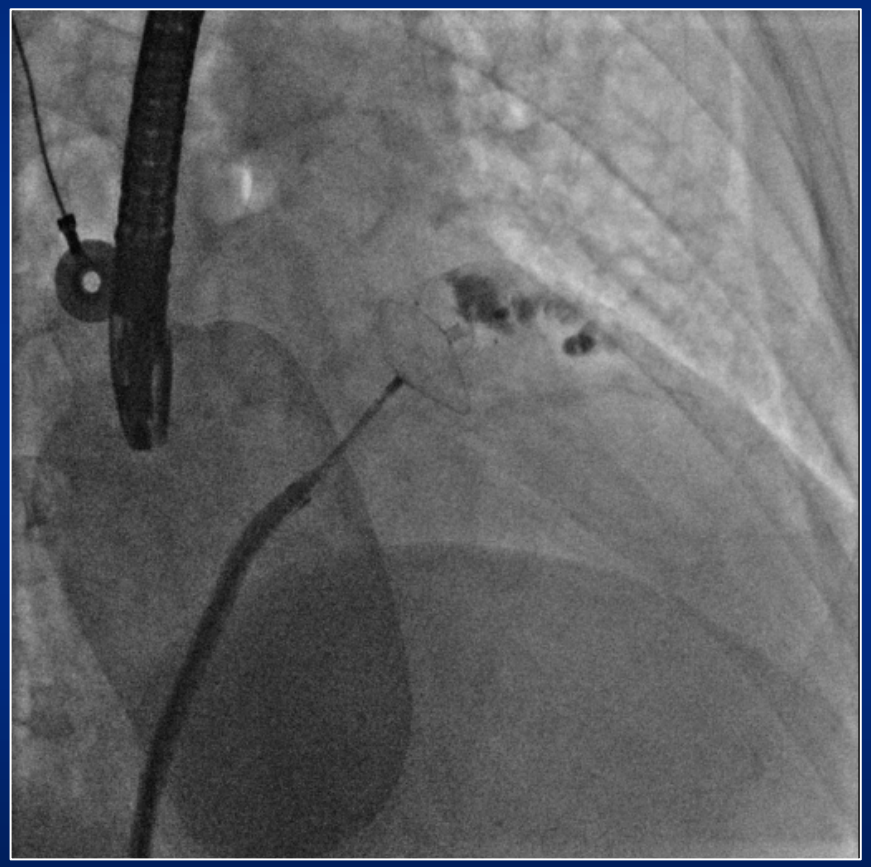
External ring disc





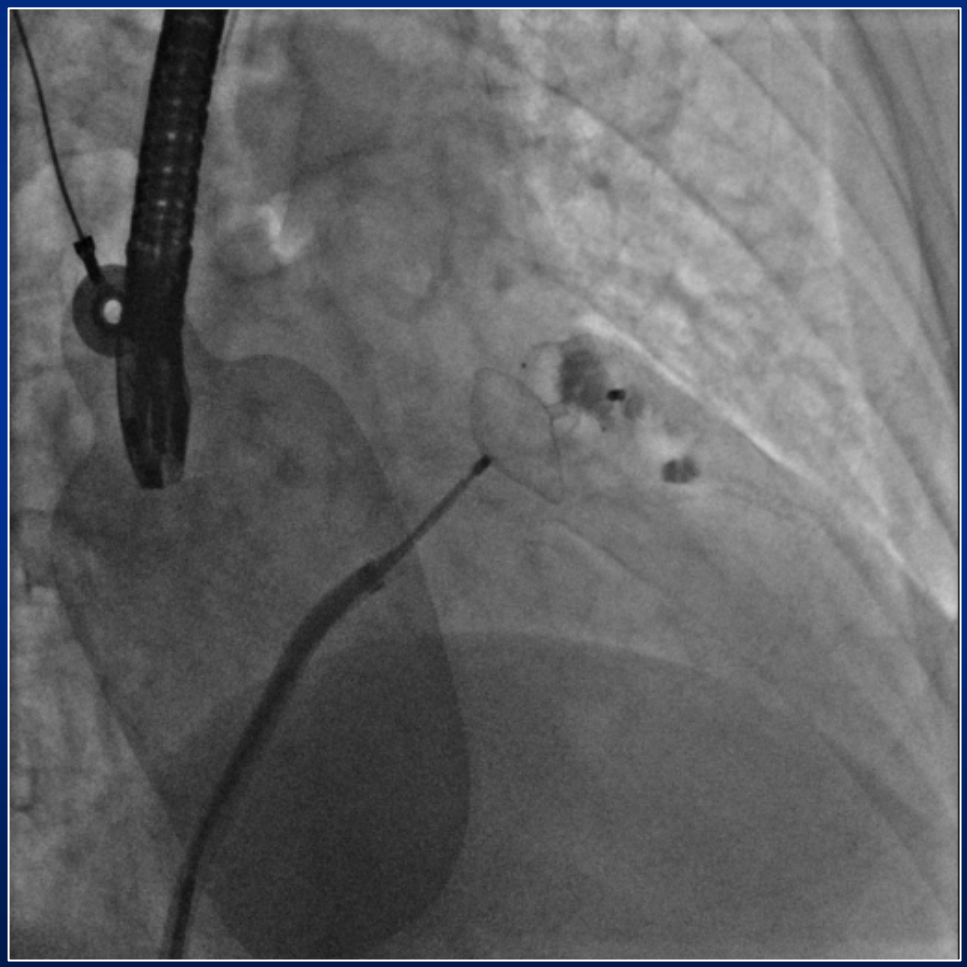
Angiographic control
Interferences





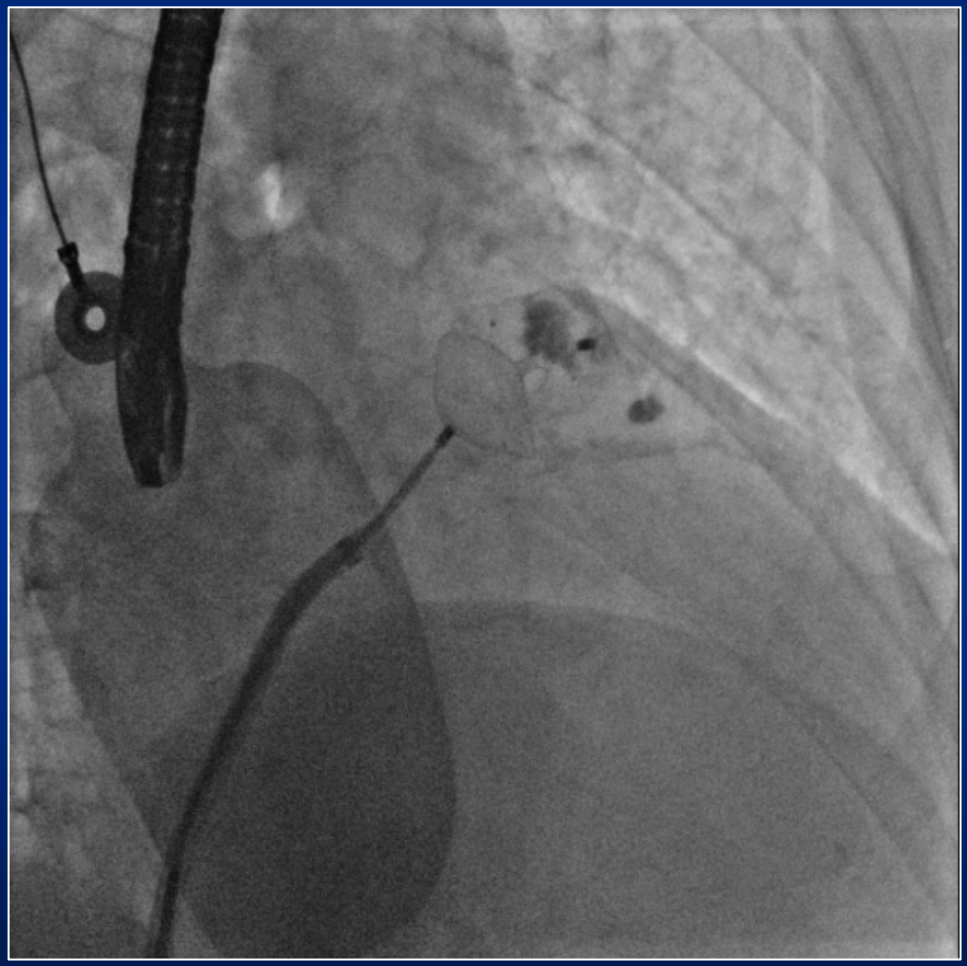
Pull trial

“Flying-disk” shape

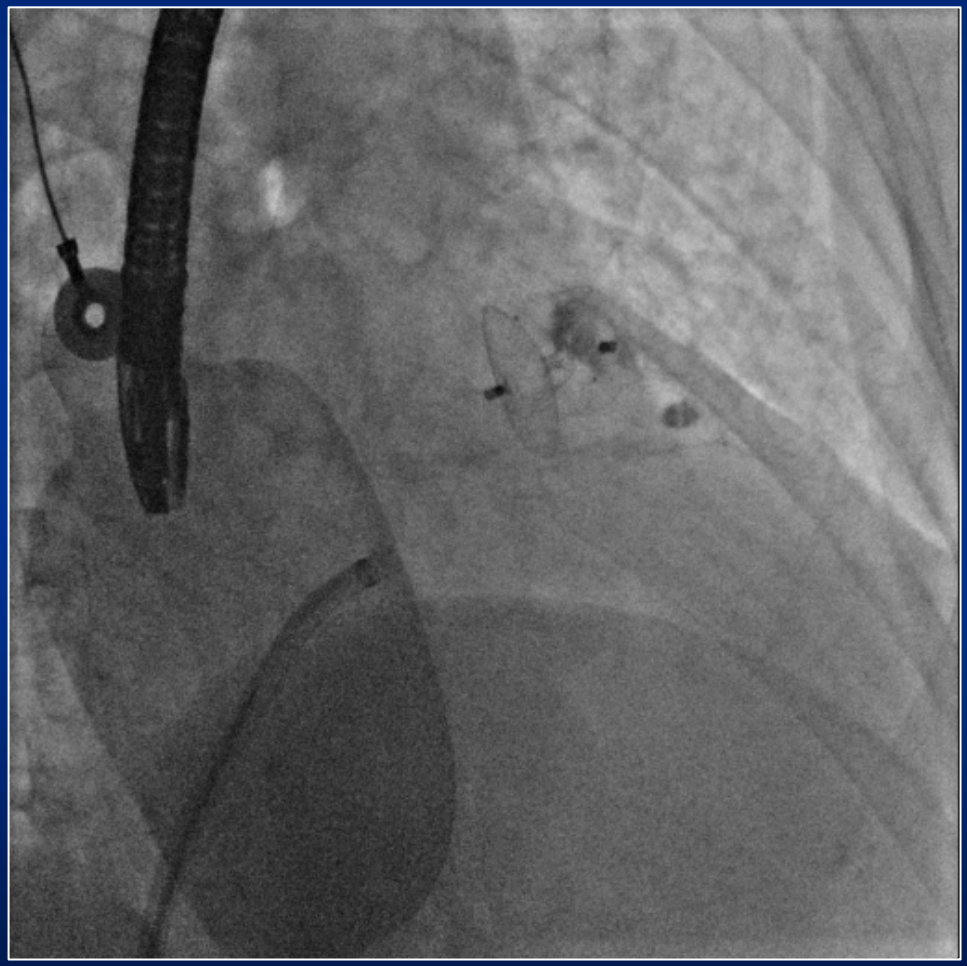


Pull image with TEE

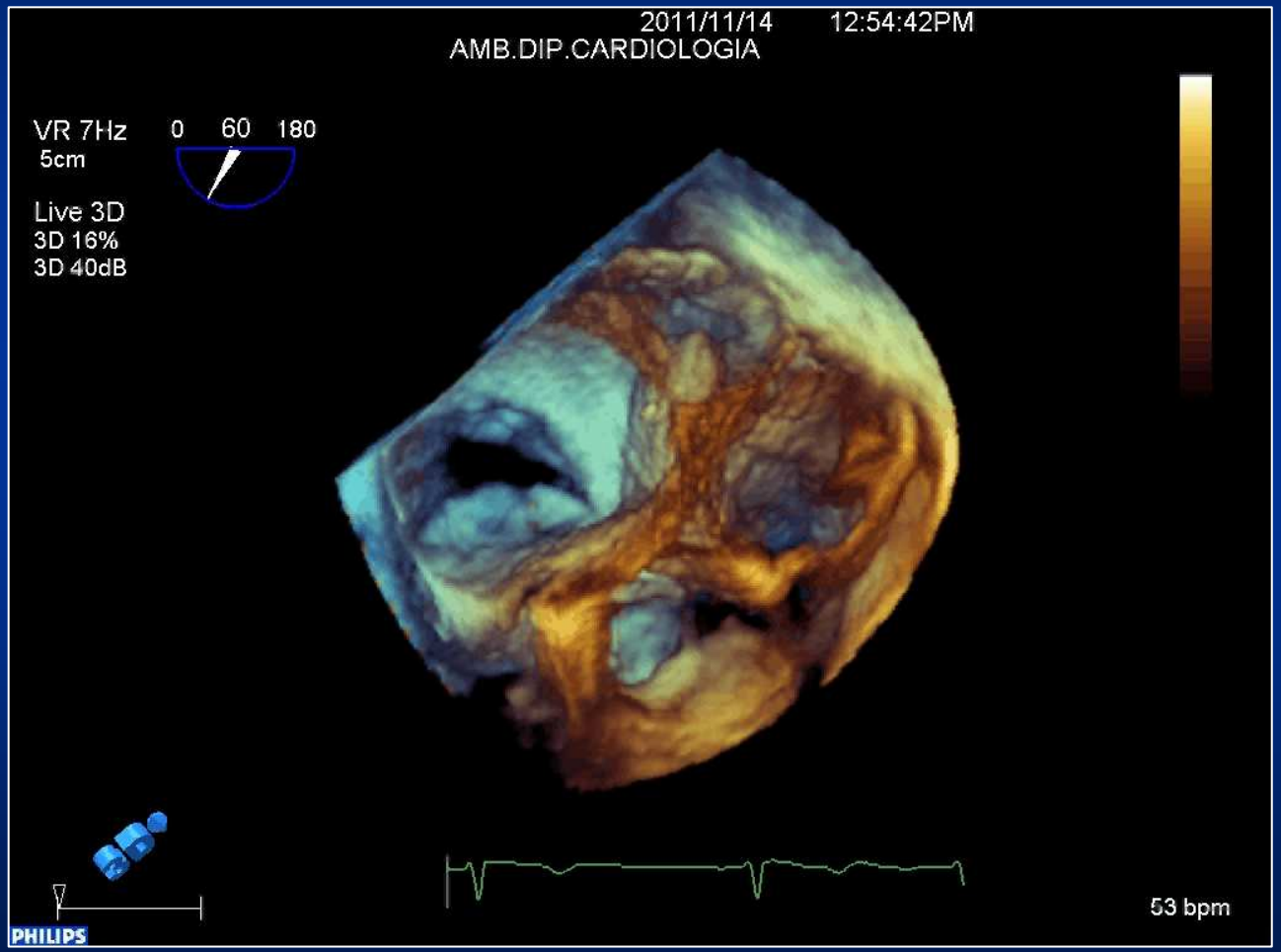
Release of device



Final Angiography



TEE 3D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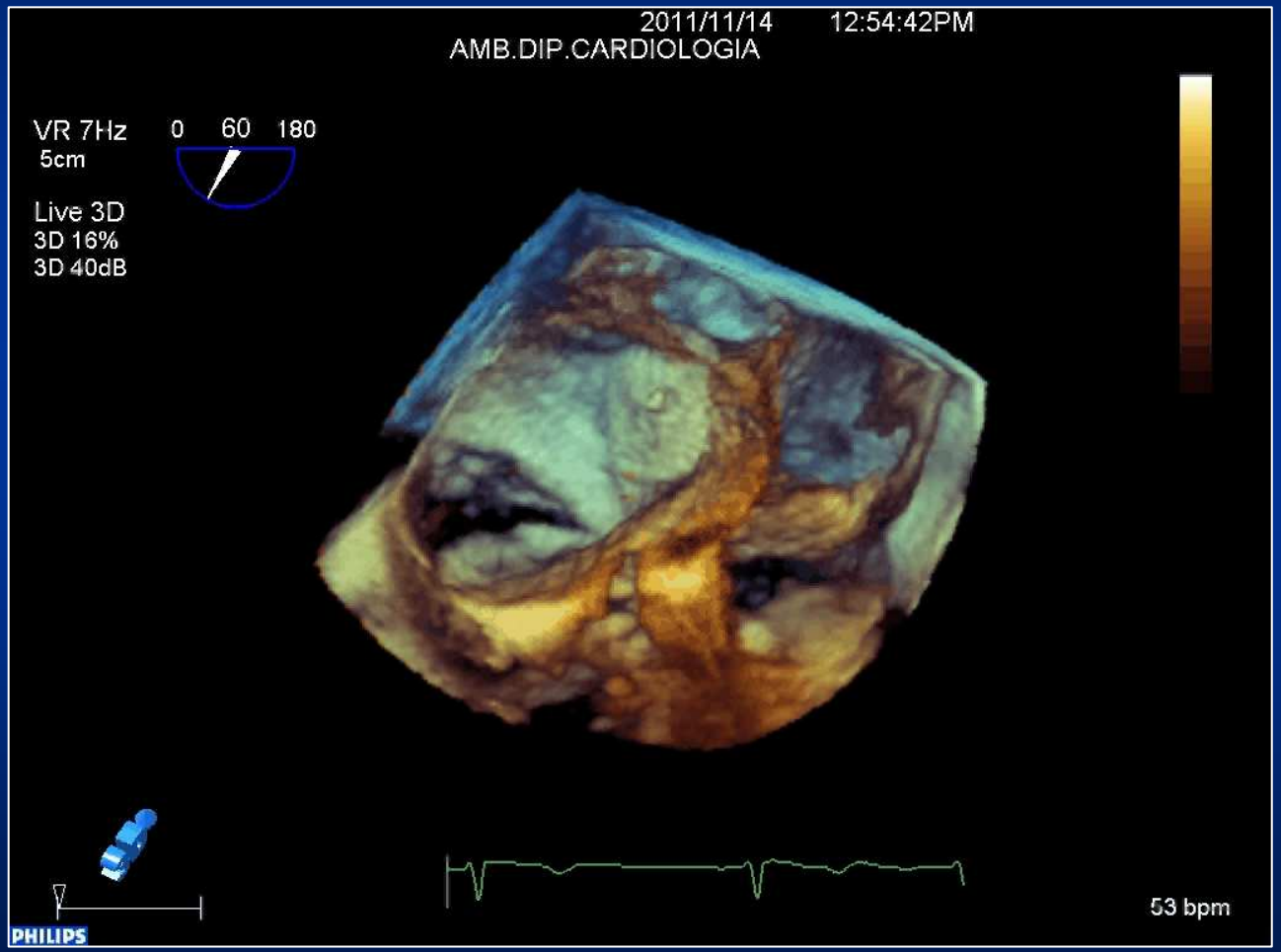
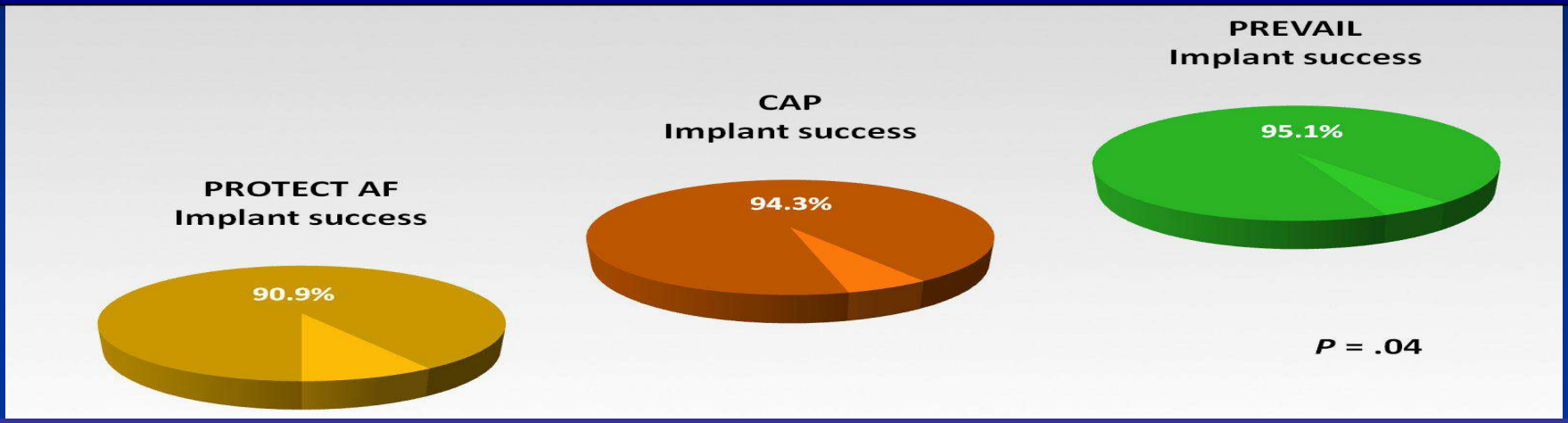
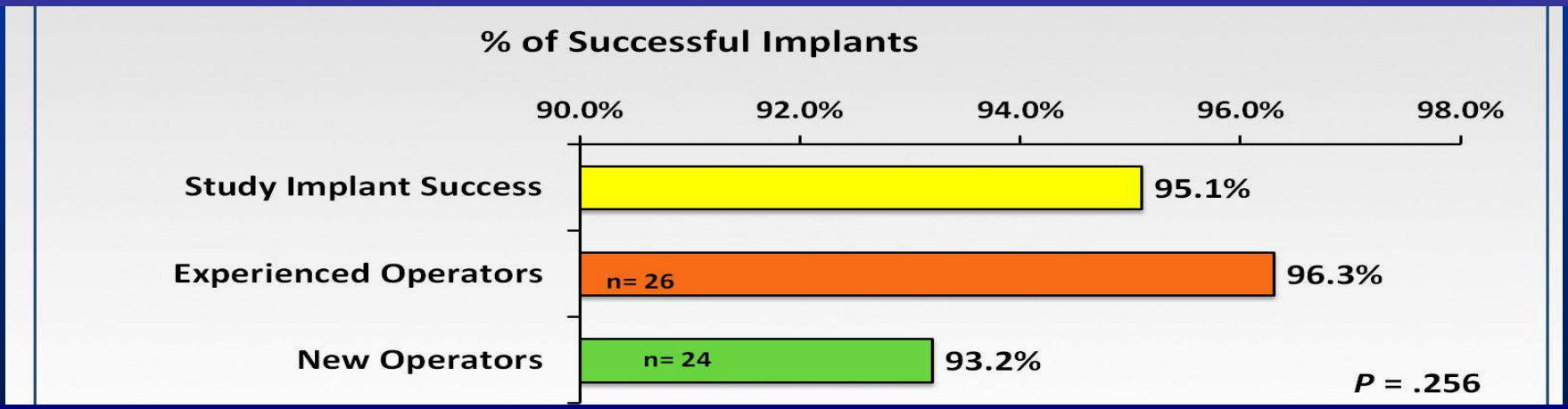
AMB.DIP.CARDIOLOGIA
VR 7Hz
5cm
0 60 180
Live 3D
3D 16%
3D 40dB
53 bpm
PHILIPS

TEE 3D


2011/11/14 12:54:42PM
AMB.DIP.CARDIOLOGIA
VR 7Hz
5cm
0 60 180
Live 3D
3D 16%
3D 40dB
53 bpm
PHILIPS

Procedural Implant Success





Complications

PERICARDIAL EFFUSION

DEVICE EMBOLIZATION

ISCHAEMIC STROKE

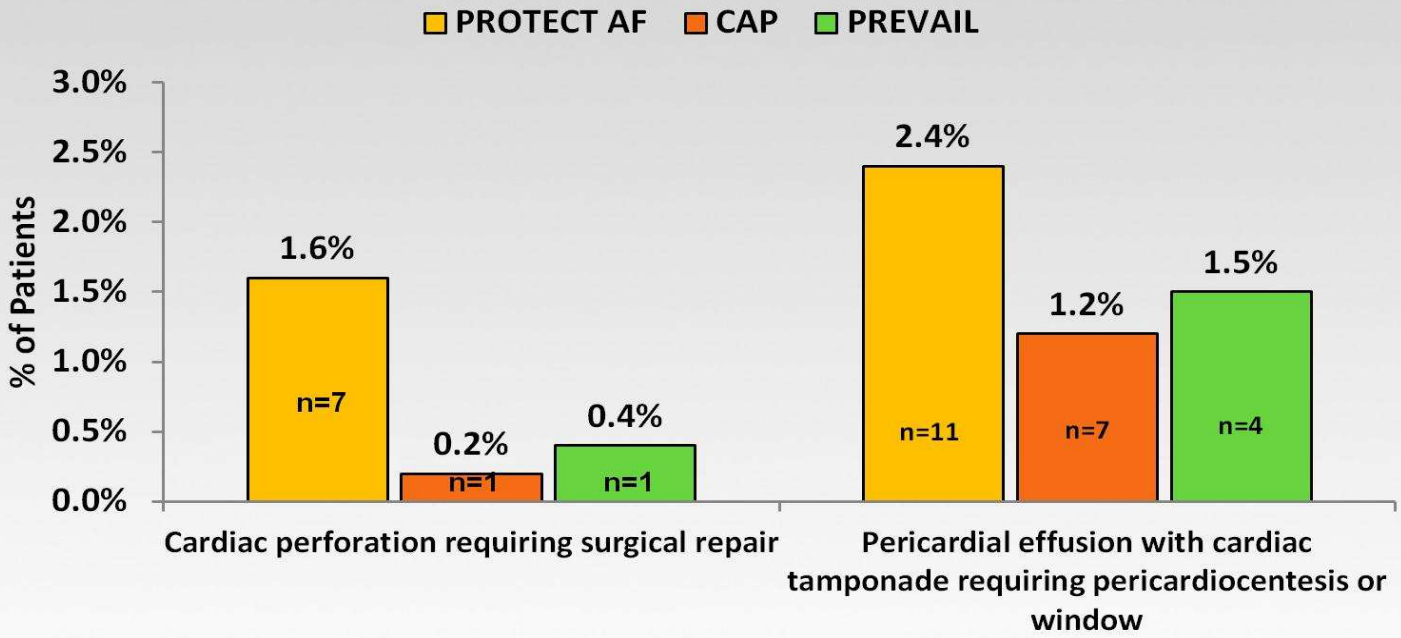
TROMBUS FORMATION

LAA Adverse Events

Study	Holmes et al. PROTECT-AF	Reddy et al. CAP	Park et al. Initial European registry	Park et al. Dual center Experience	Walsh et al. ACP EU Observ. Study	Santoro et al. Italian registry	Meerkin et al. Initial single Center experience	Lam et al. Initial Asia-Pacific Experience	Kefer et al. Belgian Registry	Walsh et al. EU Prospective Observ. Study
Device	Watchmann	Watchman	ACP	ACP	ACP	ACP	ACP	ACP	ACP	ACP
Patients enrolled	542	460	143	135	204	100	34	200	83	204
Major periprocedural complications	42 (7.7%)	17 (3.7%)	10 (7.3%)	0 (0.0%)	6 (2.9%)	1 (1.0%)	0 (0.0%)	6 (3.0%)	3 (3.6%)	6 (2.9%)
Stroke/MI	5	0	3	0	2	0	0	0	2	0
Device embolization	3	0	2	0	1	0	0	0	0	3
Cardiac perforation/effusion*	34	17	5	0	3	1	1	0	1	3
Minor periprocedural complications	54	N/A	7	3	N/A	3	0	2	4	N/A

* Defined as the need for percutaneous or surgical drainage

Comparison of Cardiac Perforations and Pericardial Effusions Requiring Intervention



Initial ACP Italian Experience

Follow-up: 24-h outcome after ACP implantation

90 pts treated in 16 centers

Investigators:

Dr Ambrosini, Mercogliano; Prof Bartorelli, Milan; Dr Berti, Massa; Prof Bortone, Bari; Dr Brscic, Torino; Dr Danna, Milan; Dr Franceschini, Padova; Dr Pantaleo, Rapallo; Dr Poli, Legnano; Dr Rapacciuolo, Napoli; Dr Saccà, Mirano; Prof Sangiorgi, Modena; Dr Santoro, Firenze; Dr Speciale, Roma; Prof Tondo, Milan; Dr Ussia, Catania; Dr Vignali, Parma.

Initial ACP Italian Experience

Procedural Complications (N=90)

Pericardial Effusion (documented in all 90 cases)	
Yes	1 (1.1 %)
No	89 (98.9 %)

Pericardial Tamponade (documented in all 90 cases)	
Yes	1 (1.1 %)
No	89 (98.9 %)

Minor Complications (documented in all 90 cases)	
Transient Thrombus on device cable	1 case
Air Embolism	1 case

Overall complications (documented in all 90 cases)	
Yes	4 (4.4 %)
No	86 (95.6 %)

Pericardial Effusion

Root Cause Analysis of the Pericardial Effusion in PROTECT AF

	Events, n(%)
Initial transseptal puncture	2/22 (9)
From adjunctive device to enter the LAA (such as a guidewire or catheter)	4/22 (18)
Manipulating delivery system within the LAA	3/22 (14)
Protruding delivery sheath from the Transseptal access path	2/22 (9)
Watchman deployment process	4/22 (18)
No definitive cause identified	7/22 (32)

Circulation. 2011;123:417-424.

Conclusion

A standardized tecnique is crucial in order to decrease the learning curve effect.

As with all interventional procedures, there is a significant improvement in the safety of LAA appendage closure with increased operator experience