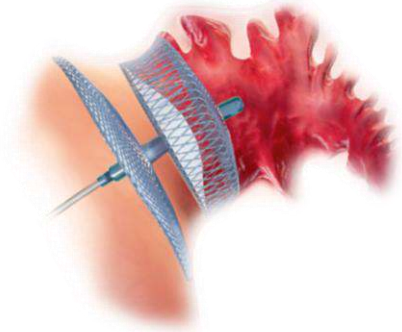
XLVII JORNADA SOLACI 16º Región Andina. *16 y 17 de Noviembre de 2023*, Lima-Perú

Cierre percutáneo de la orejuela izquierda: Watchman Flex



Ricardo Quizhpe, MD

Director, Cardiac Catheterization Laboratory

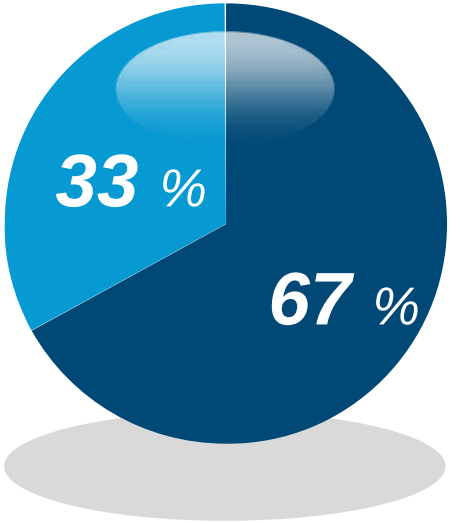
Hospital Santa Inés
Cuenca-Ecuador

Disclosure Statement of Financial Interest

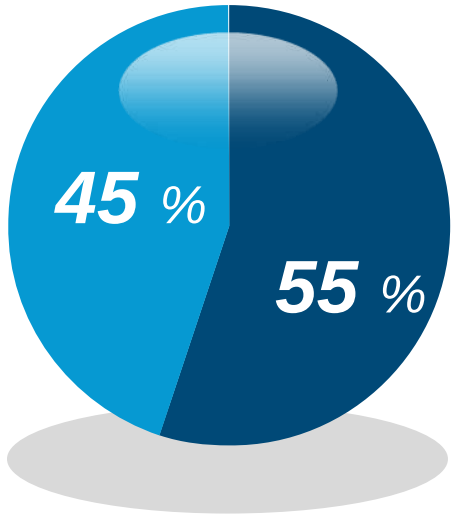
I, Ricardo Quizhpe, DO NOT have a financial interest in the subject of this presentation.

Reality: VKA in practice have poor adherence to recommendations

33 to 45 % of patients eligible to VKA do not receive VKA treatment



N = 5 333
EuroHeart survey [1]



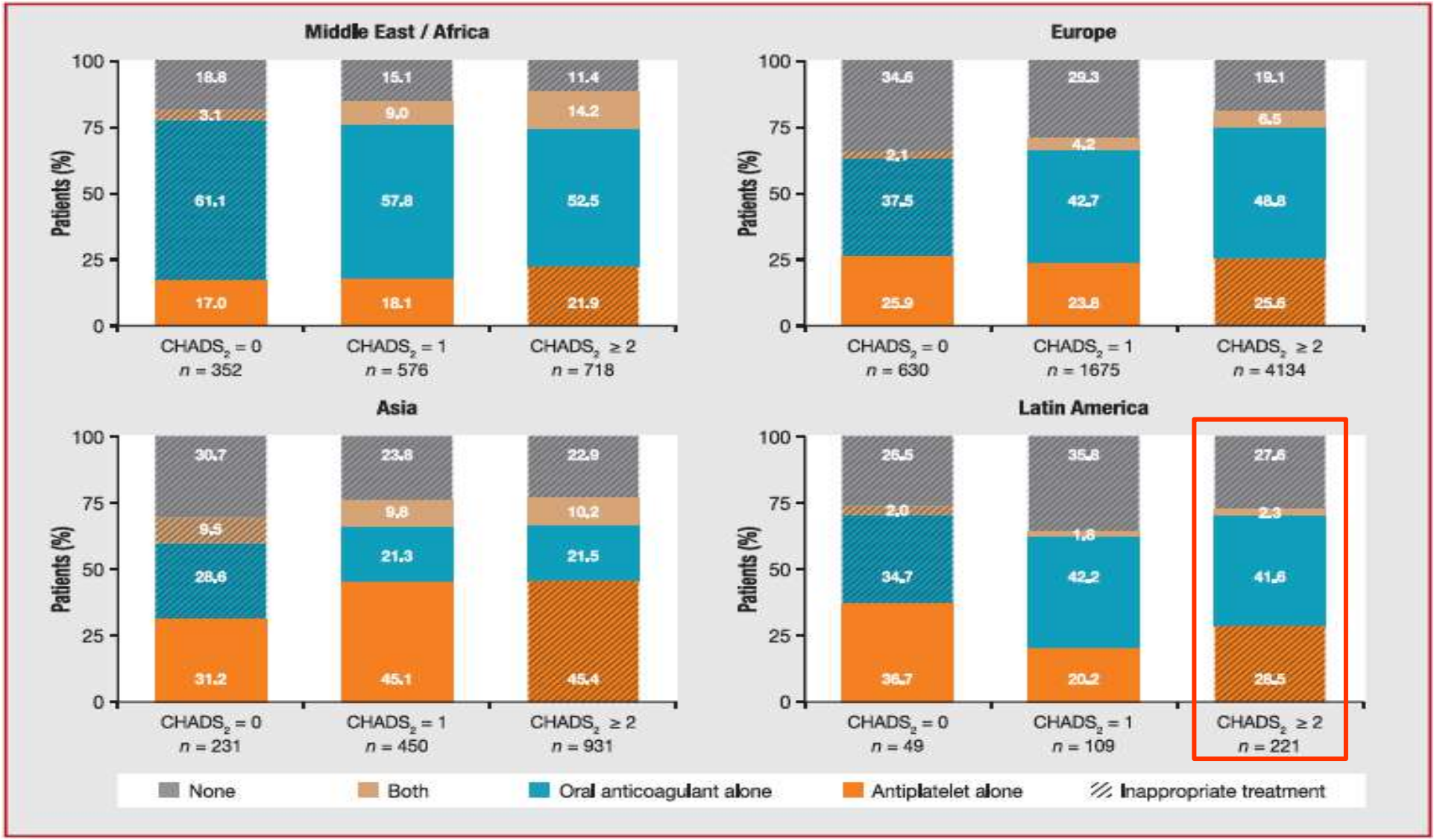
N = 11 082
ATRIA cohort [2]
(managed care system, California, USA)

No anticoagulation therapy

VKA

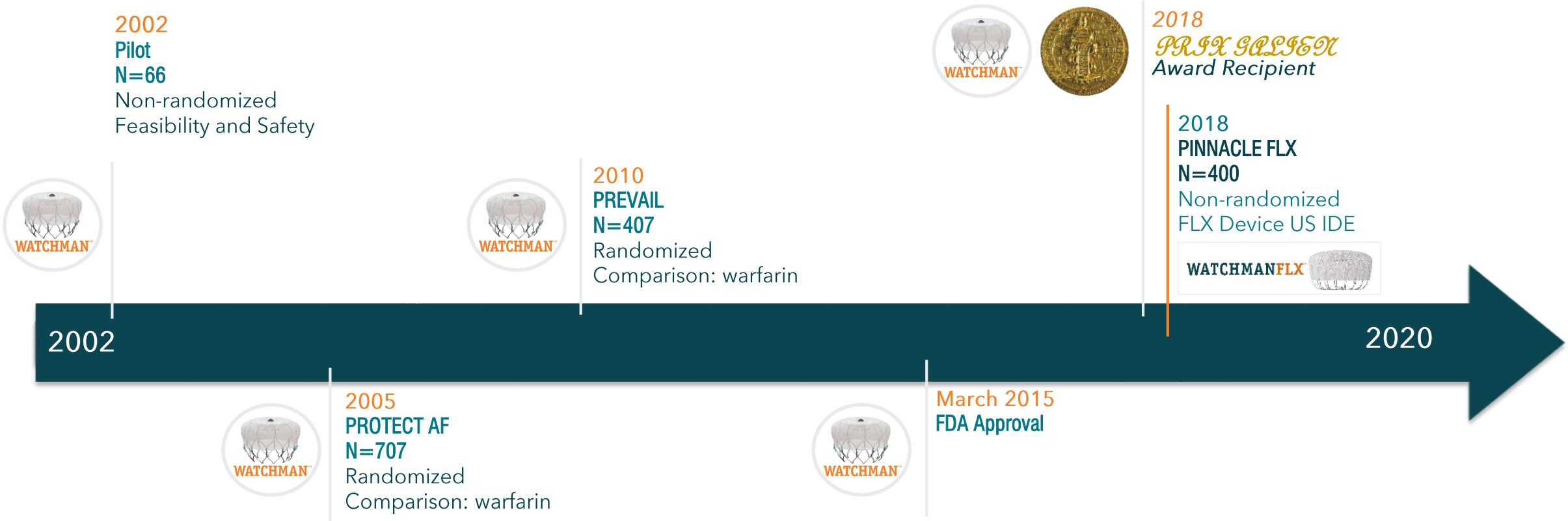
1. Nieuwlaat R et al. Atrial fibrillation management: a prospective survey in ESC Member Countries The Euro Heart Survey on Atrial Fibrillation. Eur Heart J 2005 ; 26 : 2422-2434. 2. Go AS et al. Warfarin Use among Ambulatory Patients with Nonvalvular Atrial Fibrillation : The AnTicoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study. Ann Intern Med 1999 ; 131 : 927-934

Oral Anticoagulant therapy Adherence according to Geographic Zone



H. Gamra, et al. Arc.Cardio.Vasc. 107, 2014

BUILT ON THE MOST STUDIED AND IMPLANTED LAAC DEVICE IN THE WORLD WATCHMAN FLX IS DESIGNED TO ADVANCE PROCEDURAL *PERFORMANCE AND SAFETY* WHILE EXPANDING THE TREATABLE PATIENT POPULATION



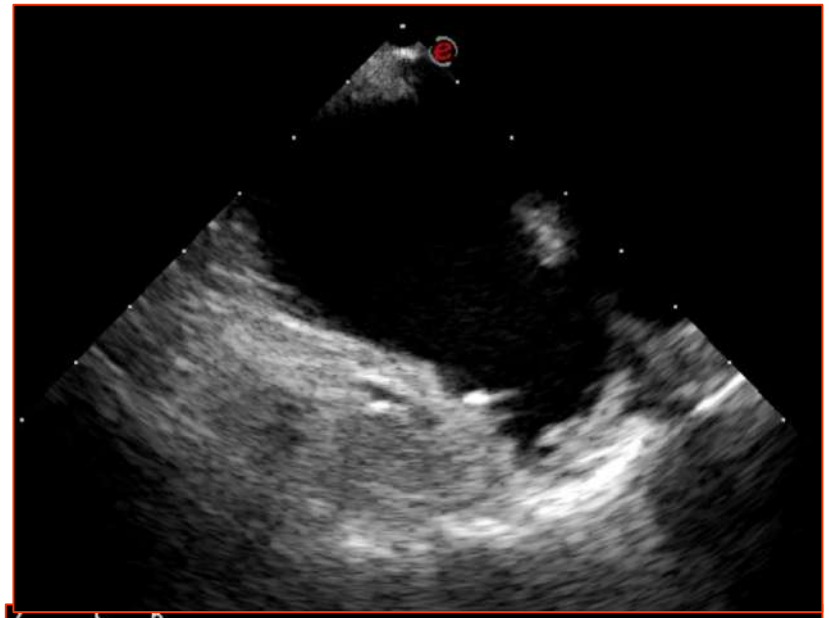
WATCHMANFLX™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

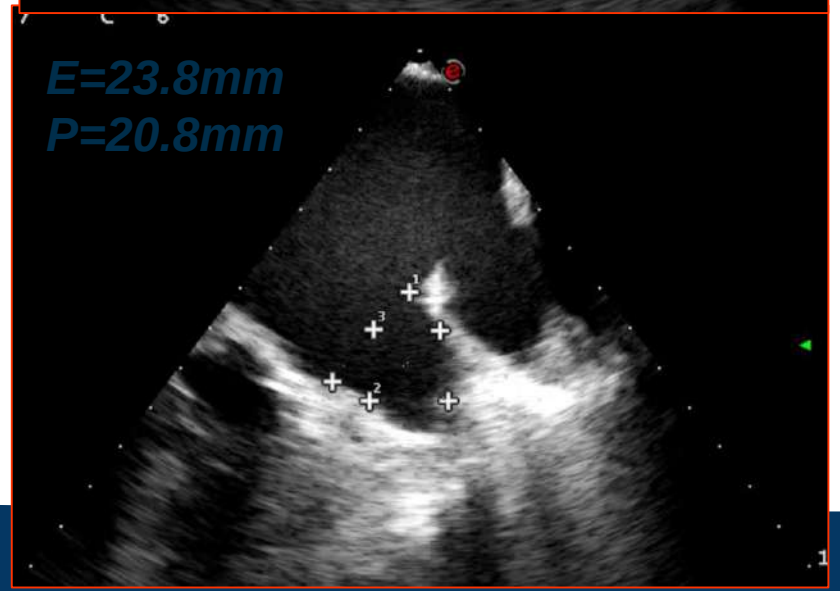
Case # 1

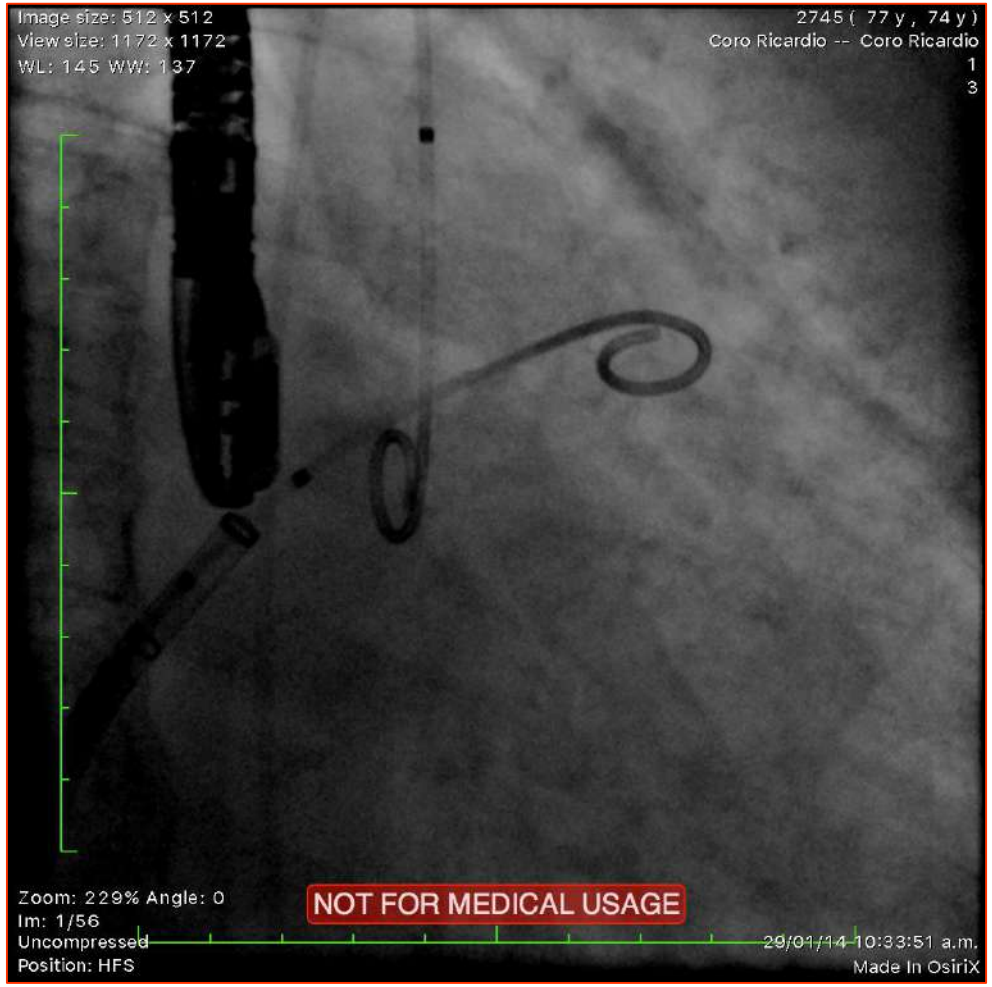
- 65 year-old lady
- Rural area residency, poor instruction.
- Chronic atrial fibrillation
- CHADS-VASc 3
- HASBLED 3
- Average of 2 outpatient visit per year

First attempt

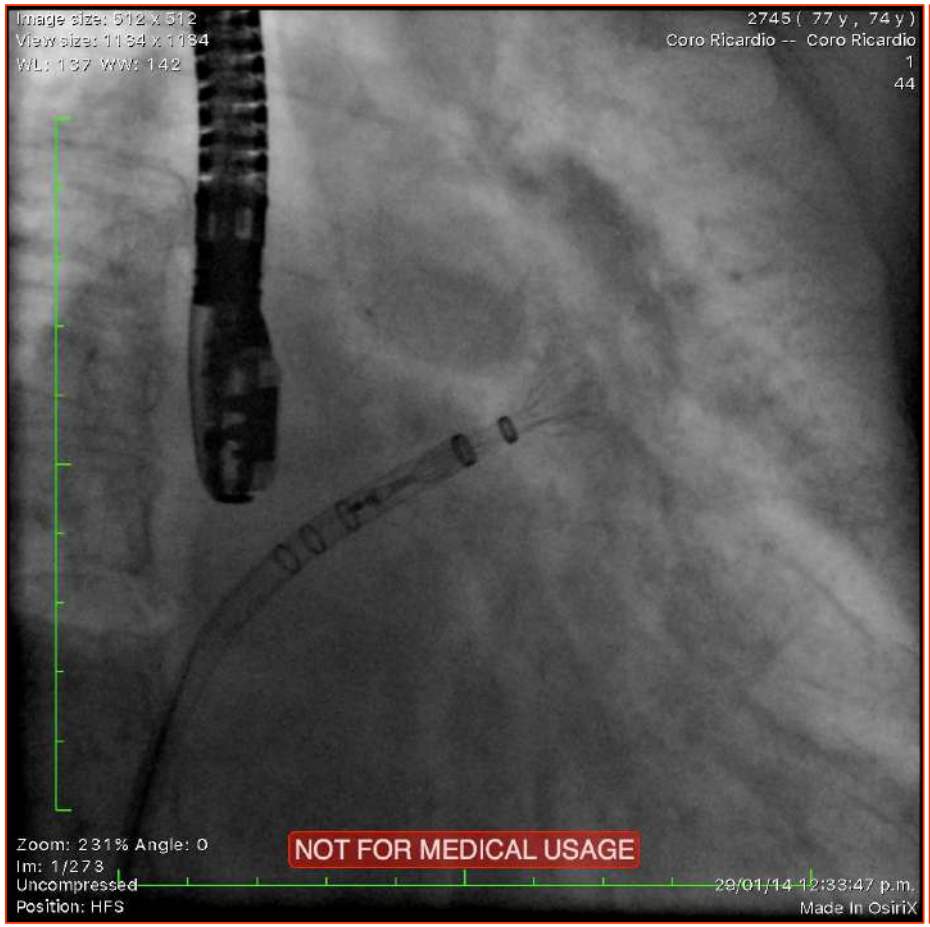
Evaluación Angiográfica y Ecocardiográfica – 1º Intento

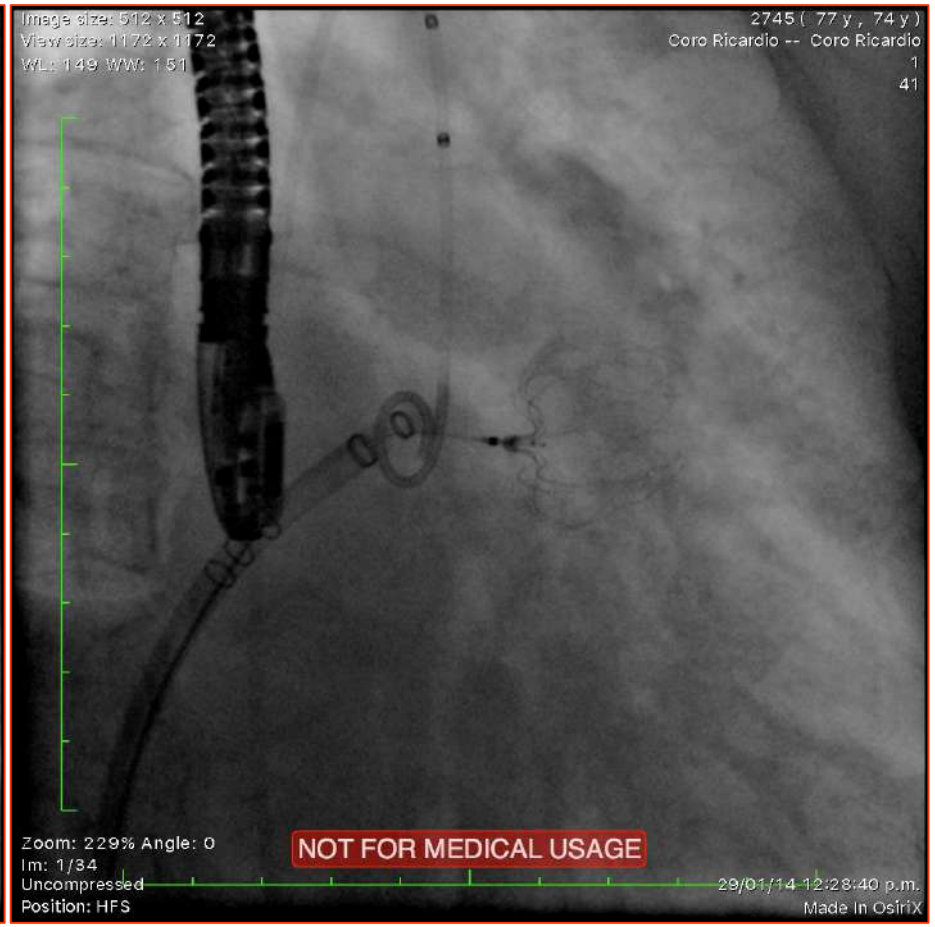






1 attempt with Watchman device



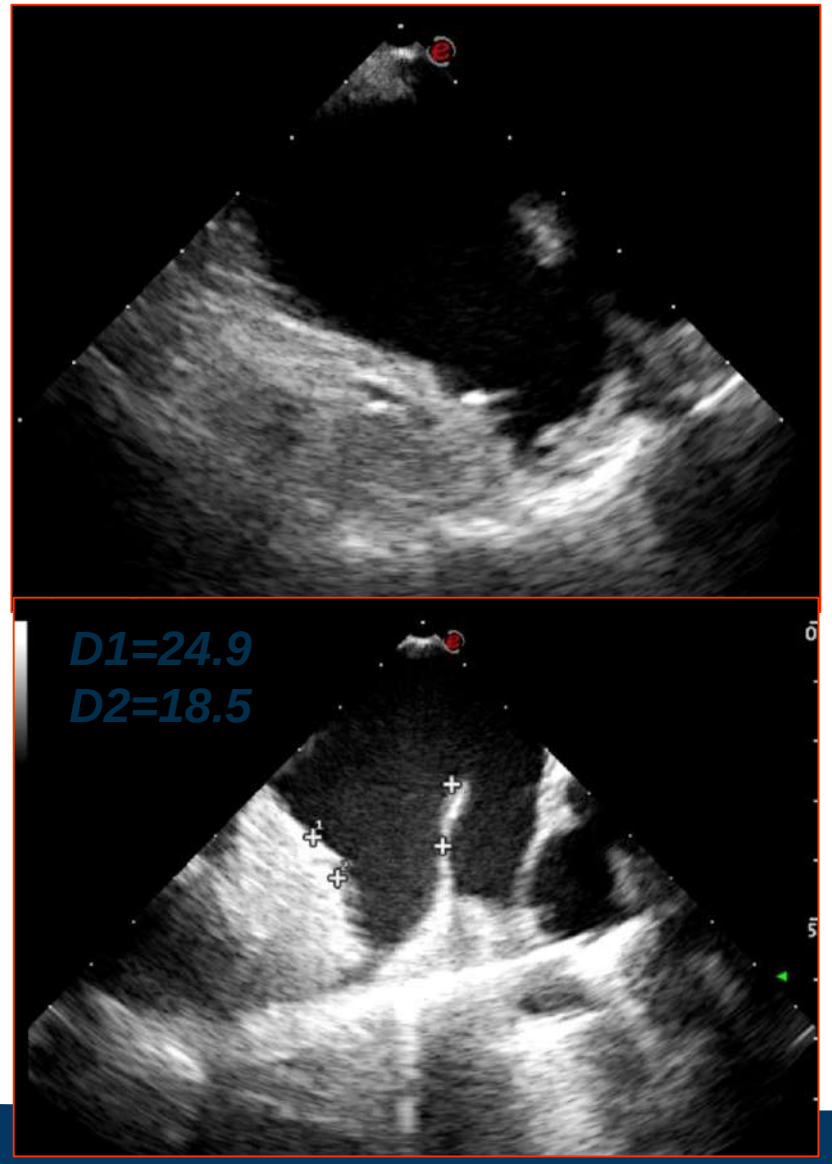


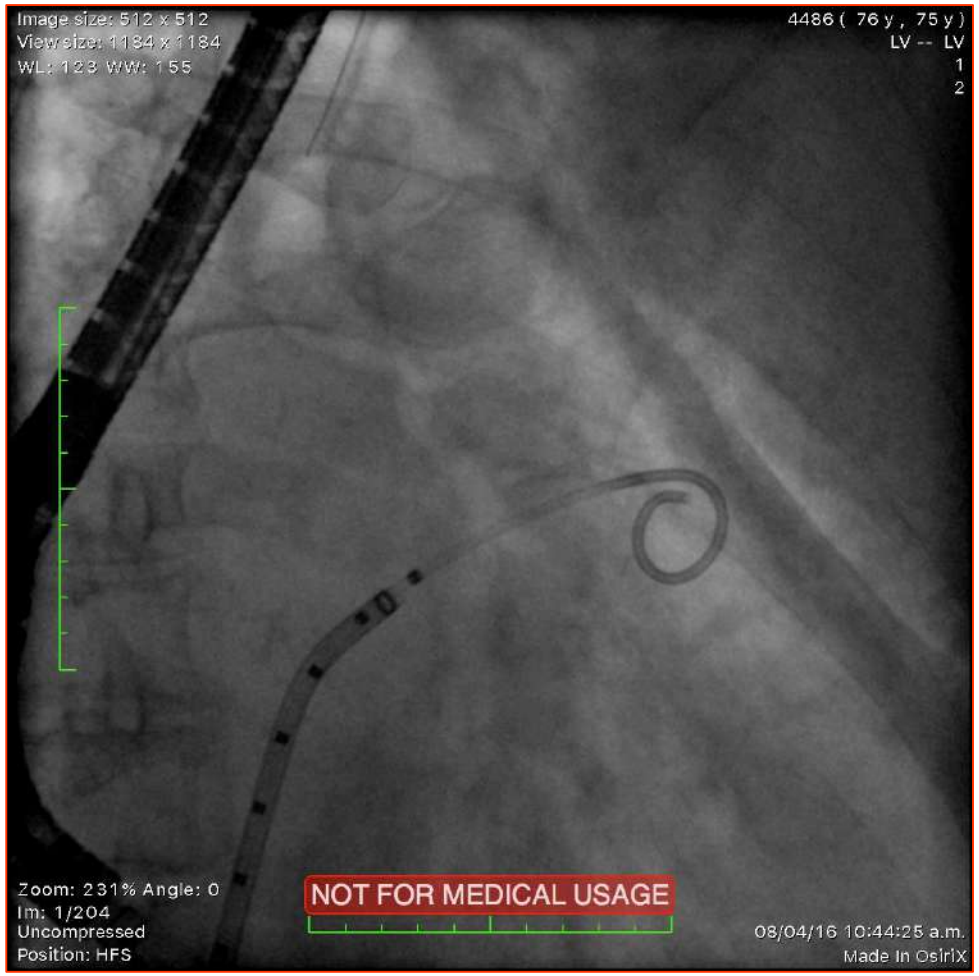
Watchman 24 y 27 fallidos

Protrución exagerada – hombro fuera del borde la art. Circunfleja

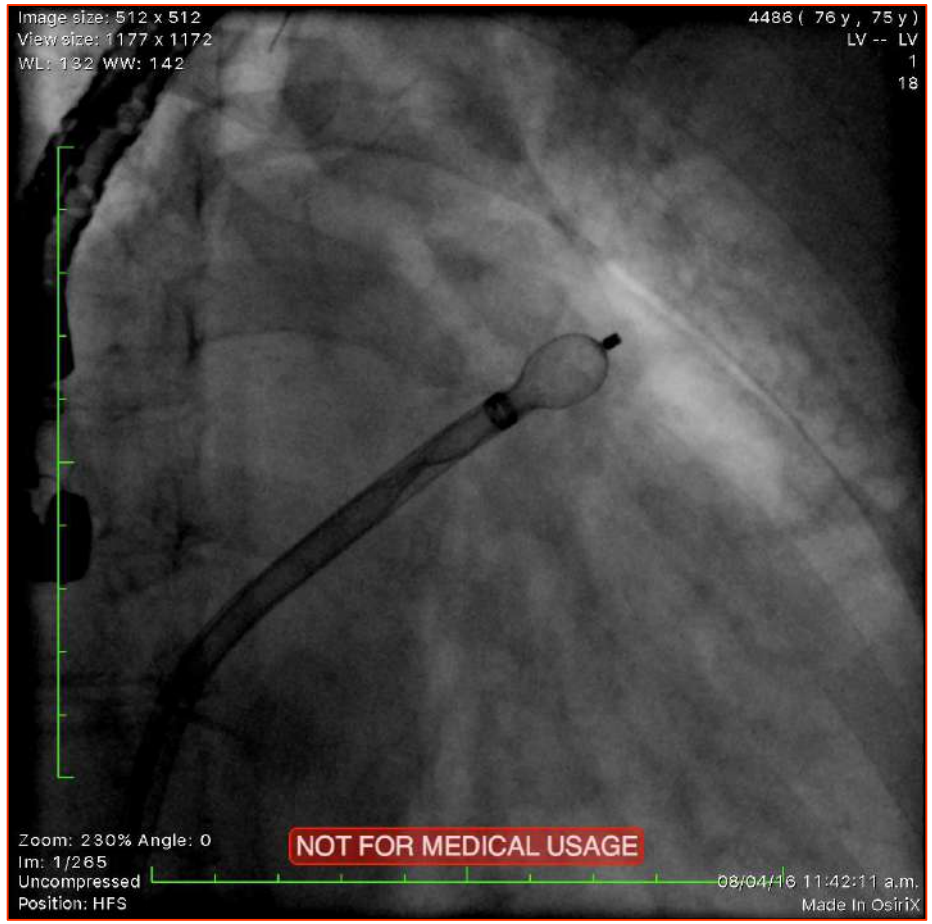
Second attempt

Evaluación Angiográfica y Ecocardiográfica – 2º Intento

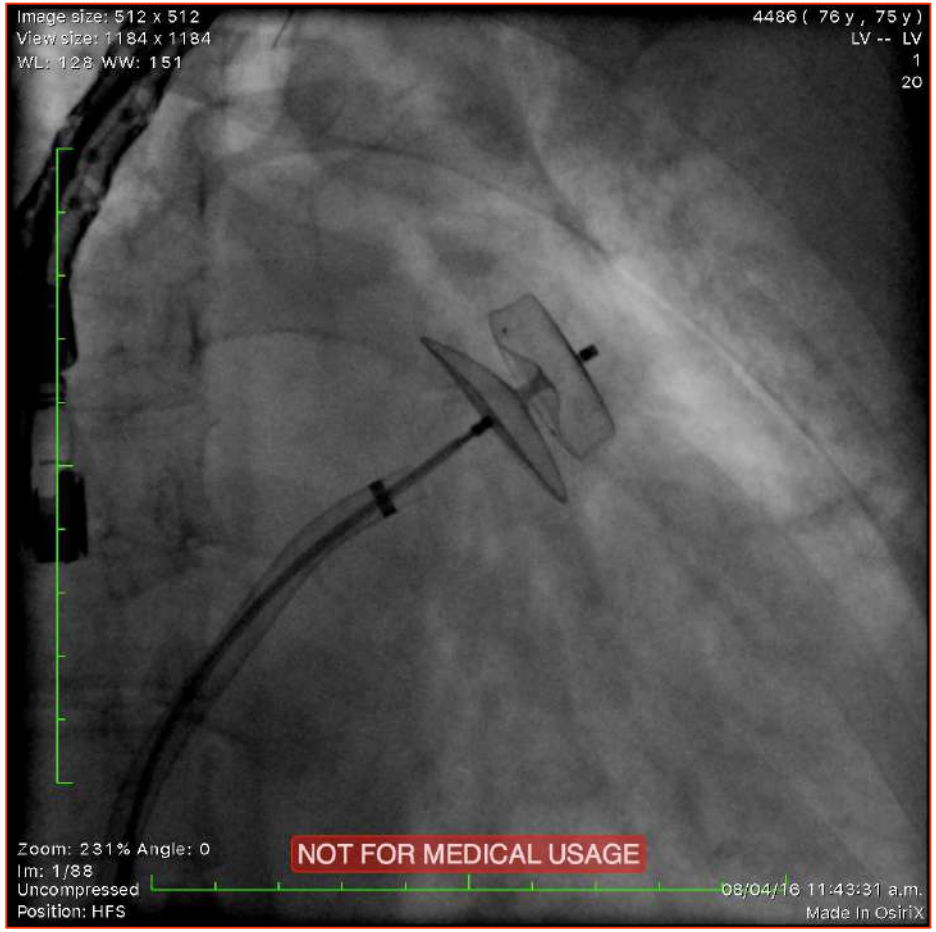




Implante de dispositivo Amulet – 2º Intento

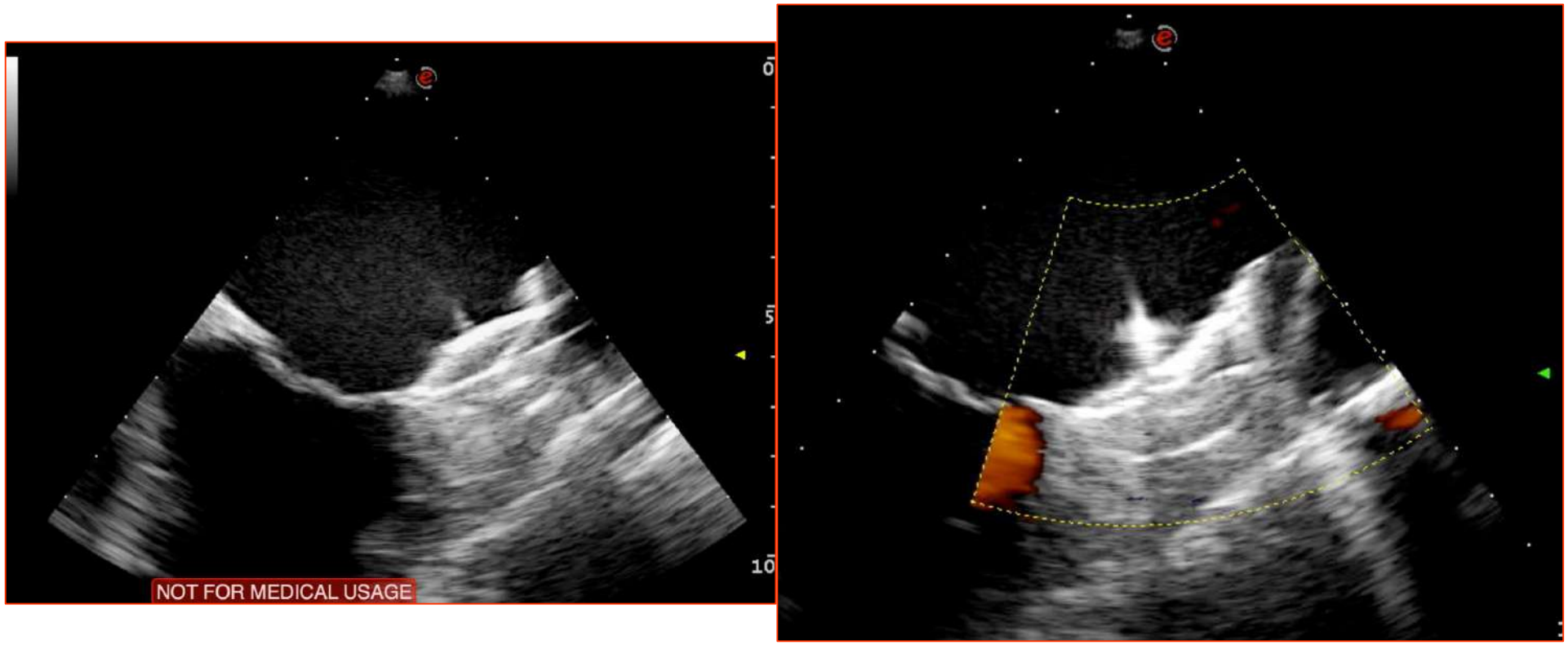


Varios intentos con dispositivo ACP 24 y Amulet 28 mm



Posicionamiento final con Amulet

Evaluación ecocardiográfica final– 2º Intento

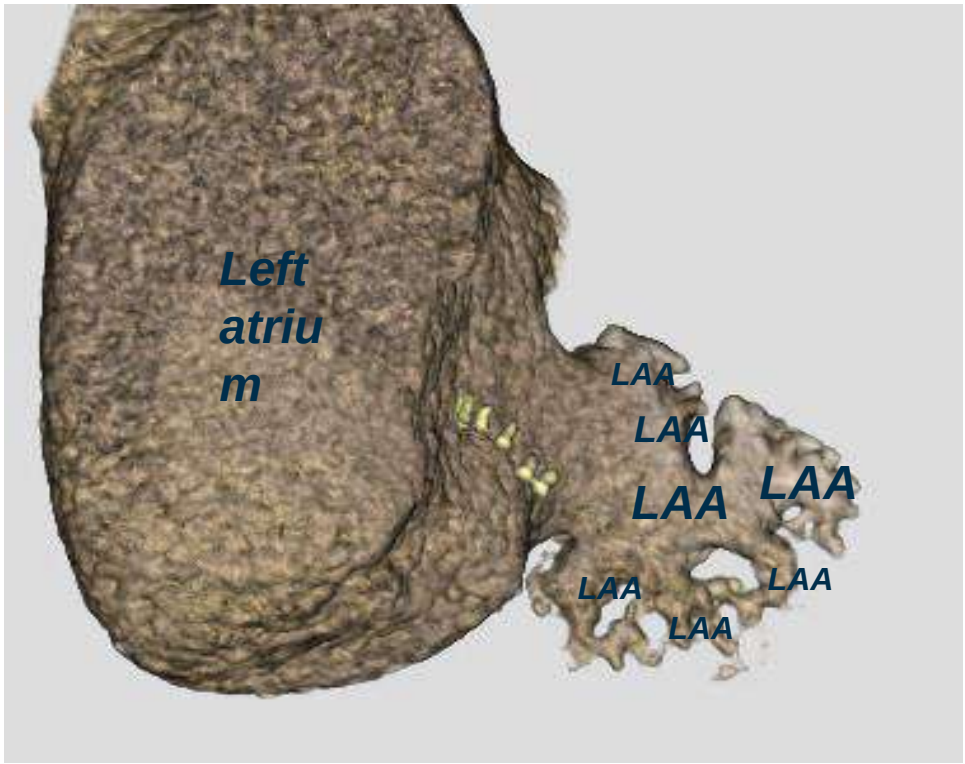


Ausencia de shunt residual

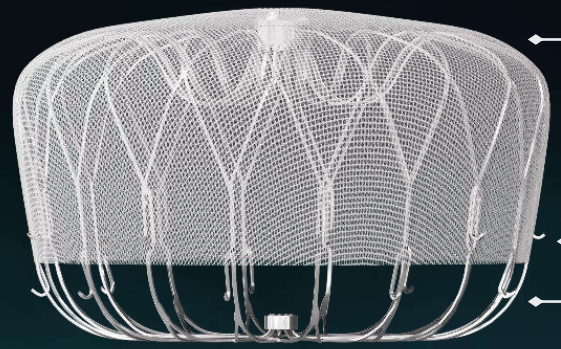
Complexity of LAA: does not have a ‘standard’ shape

Differences in angulations

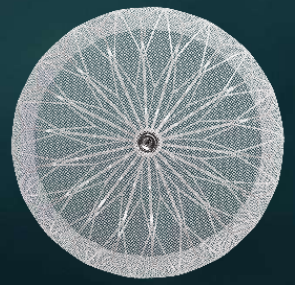
Fine details



WATCHMAN FLX™



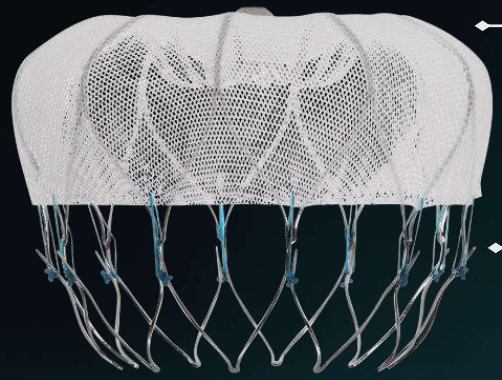
- Full recapture and redeployment
- Dual-row precision anchors
- Closed end



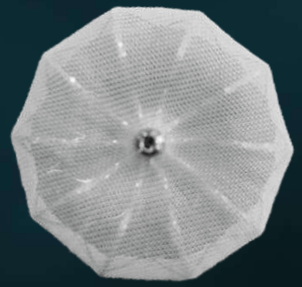
18 strut frame

Treatment range 14.0 – 31.5 mm appendages

WATCHMAN™



- Partial recapture only
- Single-row anchors
- Open end



10 strut frame

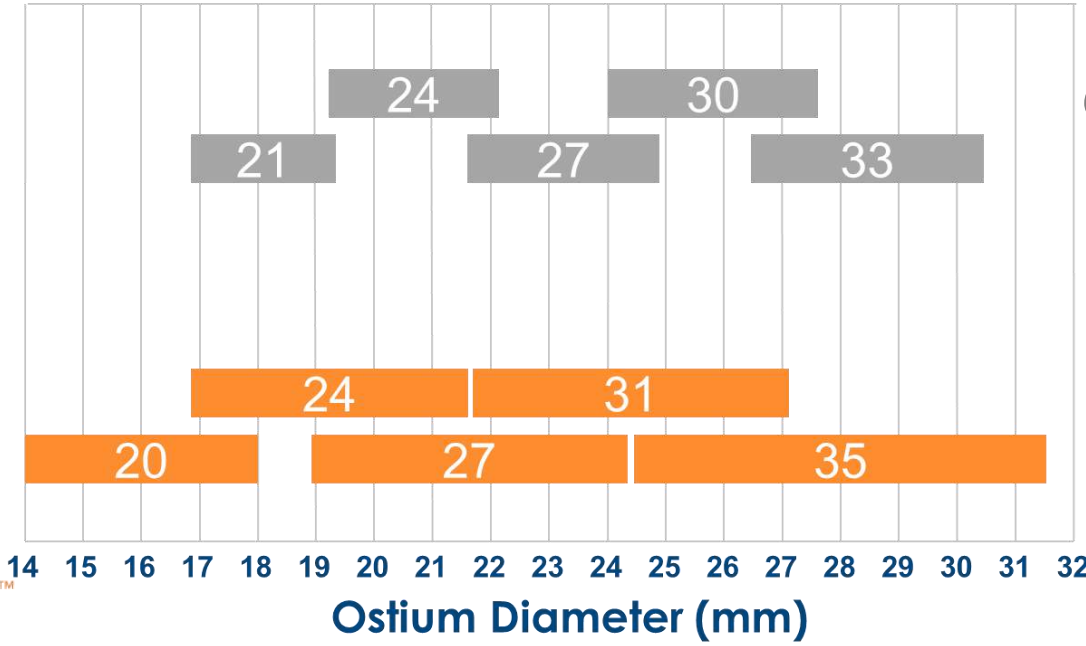
Treatment range 16.8 – 30.5 mm appendages

FLX: Wider treatment range, greater device sizing overlap

Sizing Charts

WATCHMAN™

WATCHMAN FLX™



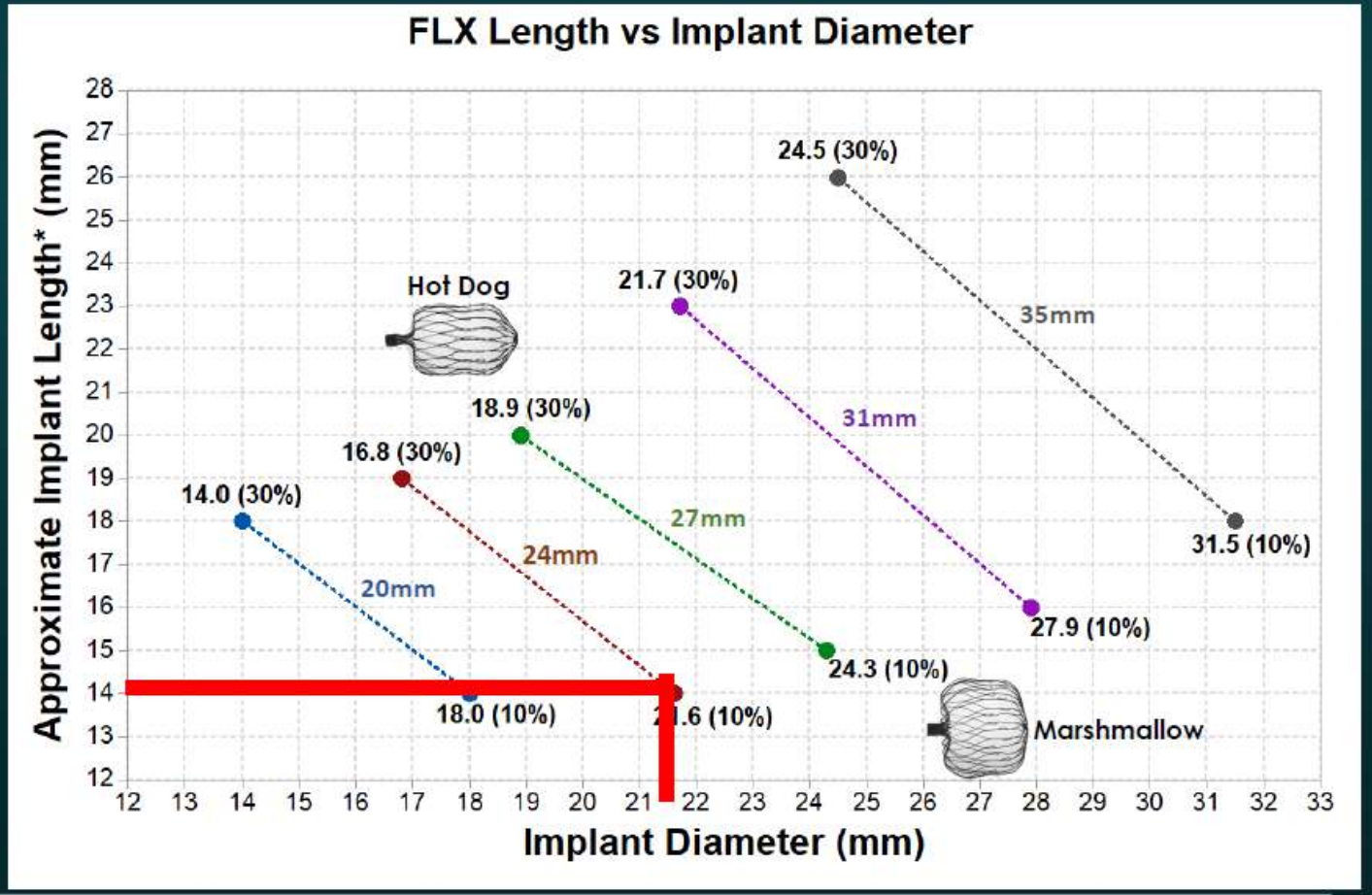
8-20% Compression

10-30% Compression

WATCHMAN FLX Sizing

Example:
21.5mm Maximum LAA OS

Options:
24mm Device: 14mm Long, 10%



SH-808904-AA-May2020

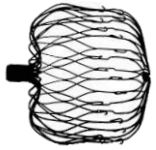
WATCHMANFLX™ LAAC DEVICE | Boston Scientific Advancing science for life™

PINNACLE FLX Procedural Data

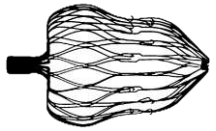
DEVICE UTILIZATION[1]

20mm	24mm	27mm	31mm	35mm
11.4%	26.8%	31.1%	22.8%	7.8%

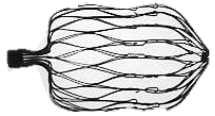
COMPRESSION[2]



MARSHMALLOW (10-16%)*



BELL (17%-23%)*



HOT-DOG (24%-30%)*

PROCEDURE[3]

MEASURE	MAIN COHORT N=400
Procedure Time	37.9 ± 21.9
Number of Implanted/Attempted WATCHMANFLX Devices	1.2 ± 0.4
WATCHMANFLX Devices Attempted	
1 Device Attempted	84.3% (337/400)
2 Devices Attempted	14.3% (57/400)
3 Devices Attempted	1.3% (5/400)
4 Devices Attempted	0.3% (1/400)
Number of Partial Recaptures[4]	1.8 ± 2.8 (400) (0.0, 24.0)
Number of Full Recaptures[4]	0.4 ± 1.1 (400) (0.0, 14.0)
[4]Implanted and Attempted Devices	

*Compression ranges corresponding to the shape categories are approximate. Shapes represented are not exclusive, as WM FLX can conform to a range of shape configurations driven by compression and anatomy.

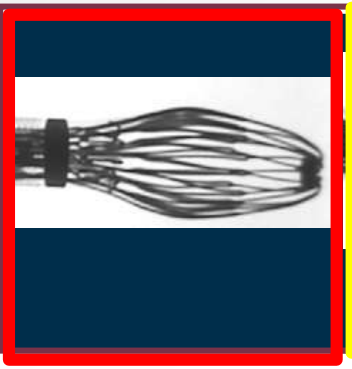
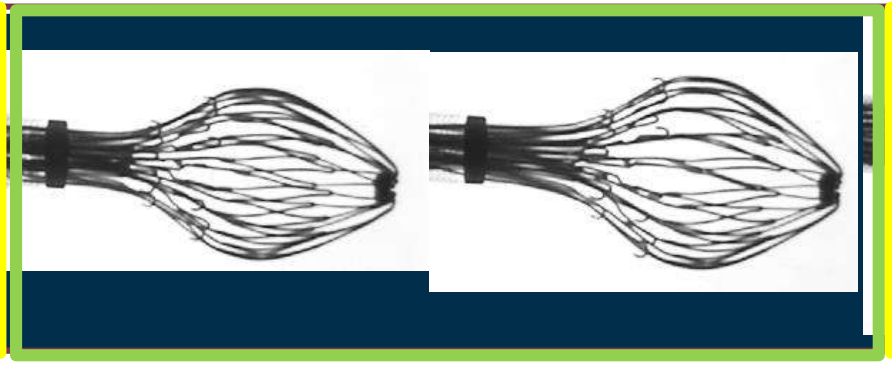
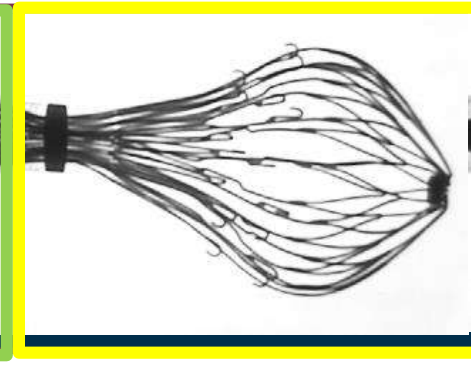
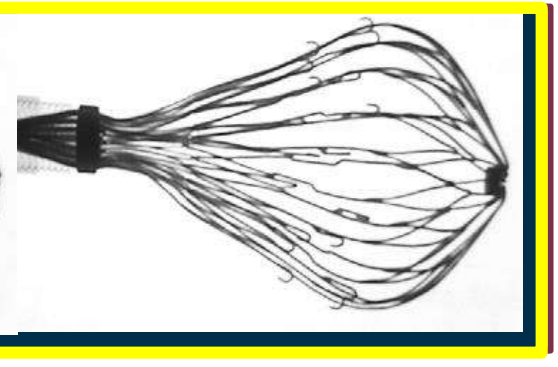
[2]Compression from main cohort using the maximum implant diameter (using TEE) as the denominator

[1]Doshi, SK. Presented at HRS 2020. SH-669512-AA.

[3]BSC Data on file

Stages of the FLX Ball

Boston Scientific

2X width not established	No anchors exposed, but ball not optimized.	Distal Anchors at the tri-cuts	Distal Anchors begin to be exposed	Distal anchors can engage tissue if pulled proximally	Both proximal and distal anchors exposed and active
					
Avoid distal motion	Avoid distal motion	Both proximal and distal repositioning acceptable.	Both proximal and distal repositioning acceptable.	Avoid proximal motion	Avoid proximal motion

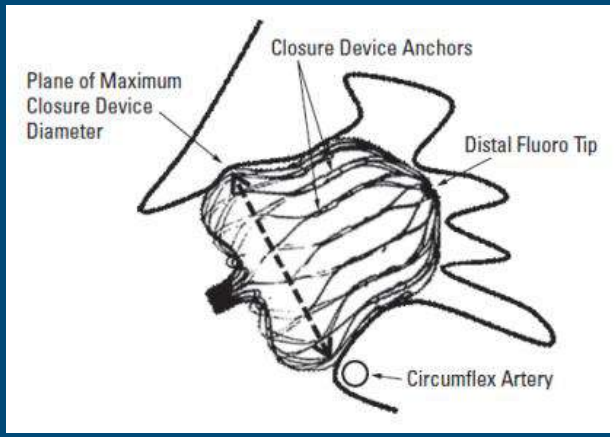
PASS Criteria

Boston Scientific

Closure Device release criteria: Position, Anchor, Size, and Seal (PASS™ criteria):

Position

- Plane of maximum diameter of the Closure Device should be at or just distal to the LAA ostium



Anchor

- Gently pull back then release deployment knob to visualize movement of Closure Device and LAA together.

Size (compression)

- Measure plane of maximum diameter of Closure Device. 10-30% Compression Range

Seal

- Ensure all lobes of the LAA are distal to Closure Device and sealed, i.e.≤ 5mm

Table 1. WATCHMAN FLX Device Selection

Max LAA Ostium Width and/or Deployed Closure Device Diameter (mm)	Closure Device Size (mm)
14.0 – 18.0	20
16.8 – 21.6	24
18.9 – 24.3	27
21.7– 27.9	31
24.5 – 31.5	35

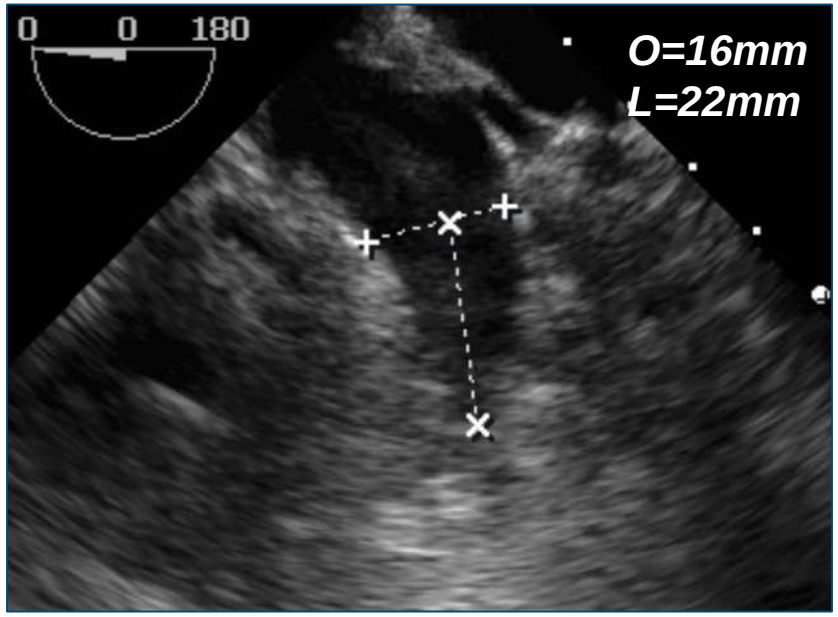
Case # 2

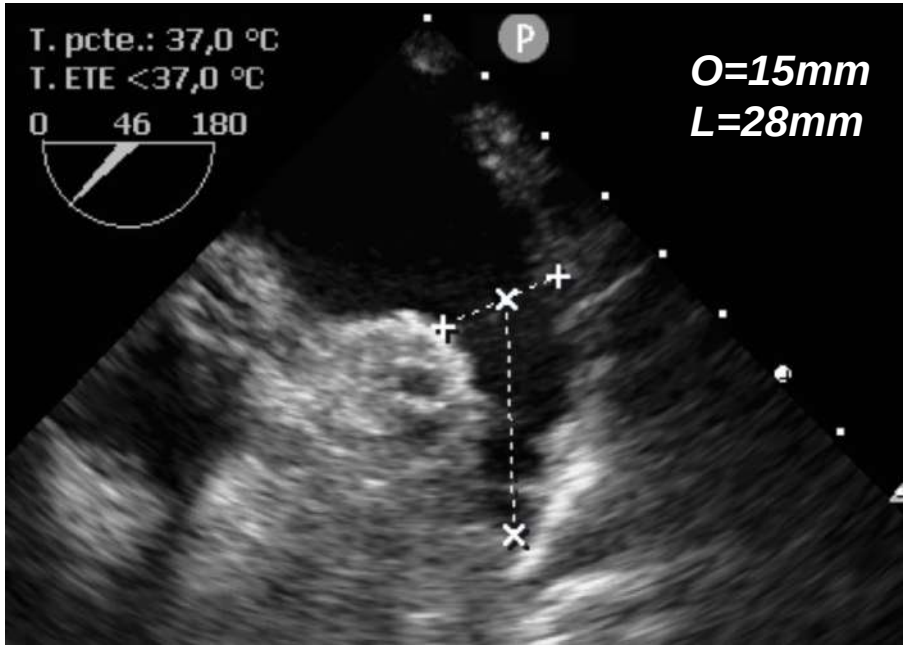
- 76 year-old lady
- Main complain: non adherence to DOAC therapy and seeking alternative strategy for stroke prevention
- Non valvular AF and long-term treatment with metoprolol
- Active life style and caring of disabled person

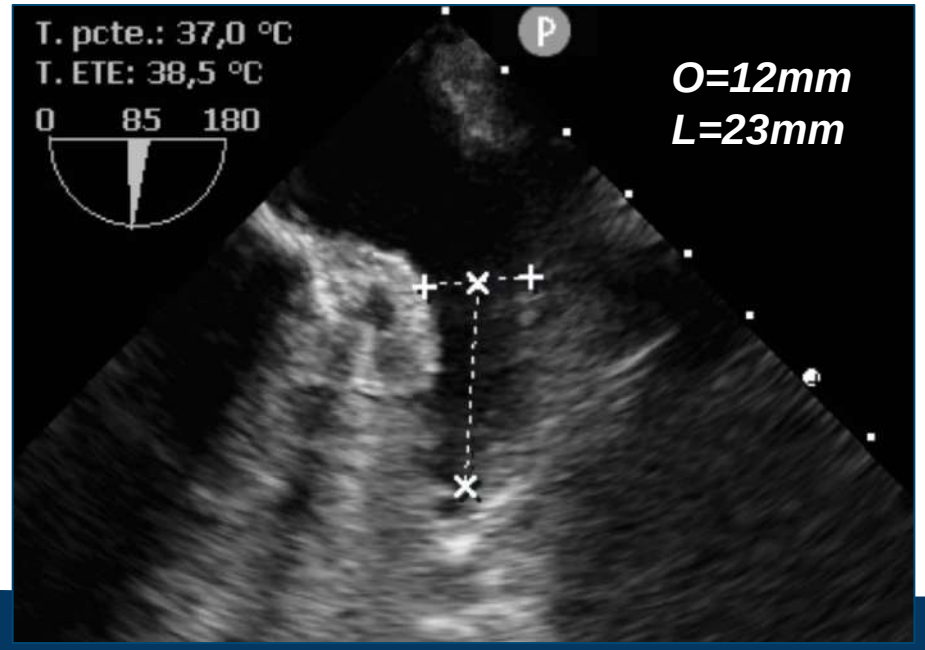
Step 1. TEE anatomy evaluation

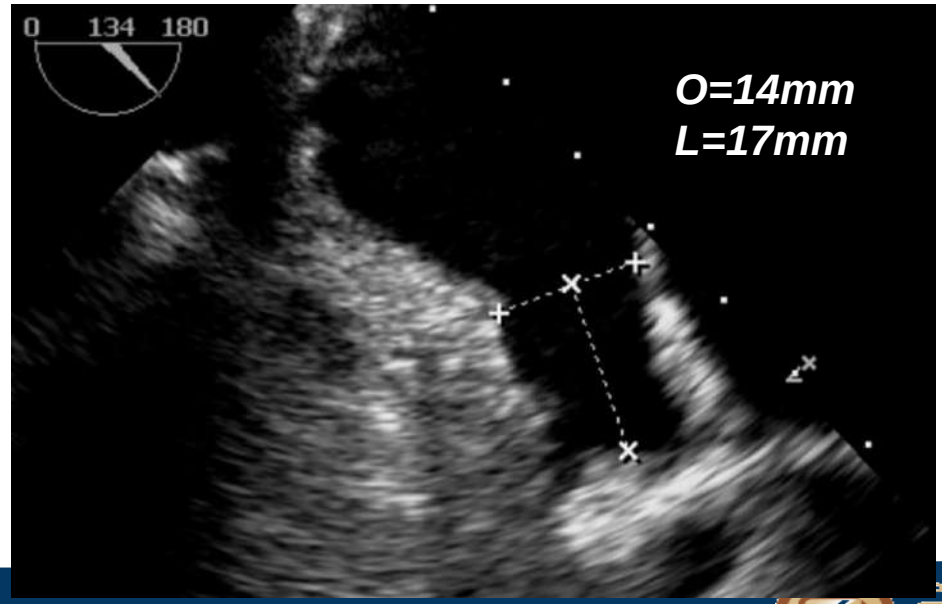
Left atrial appendage measurement in 4 views

Anatomic challenge: ***Small orifice and depth***

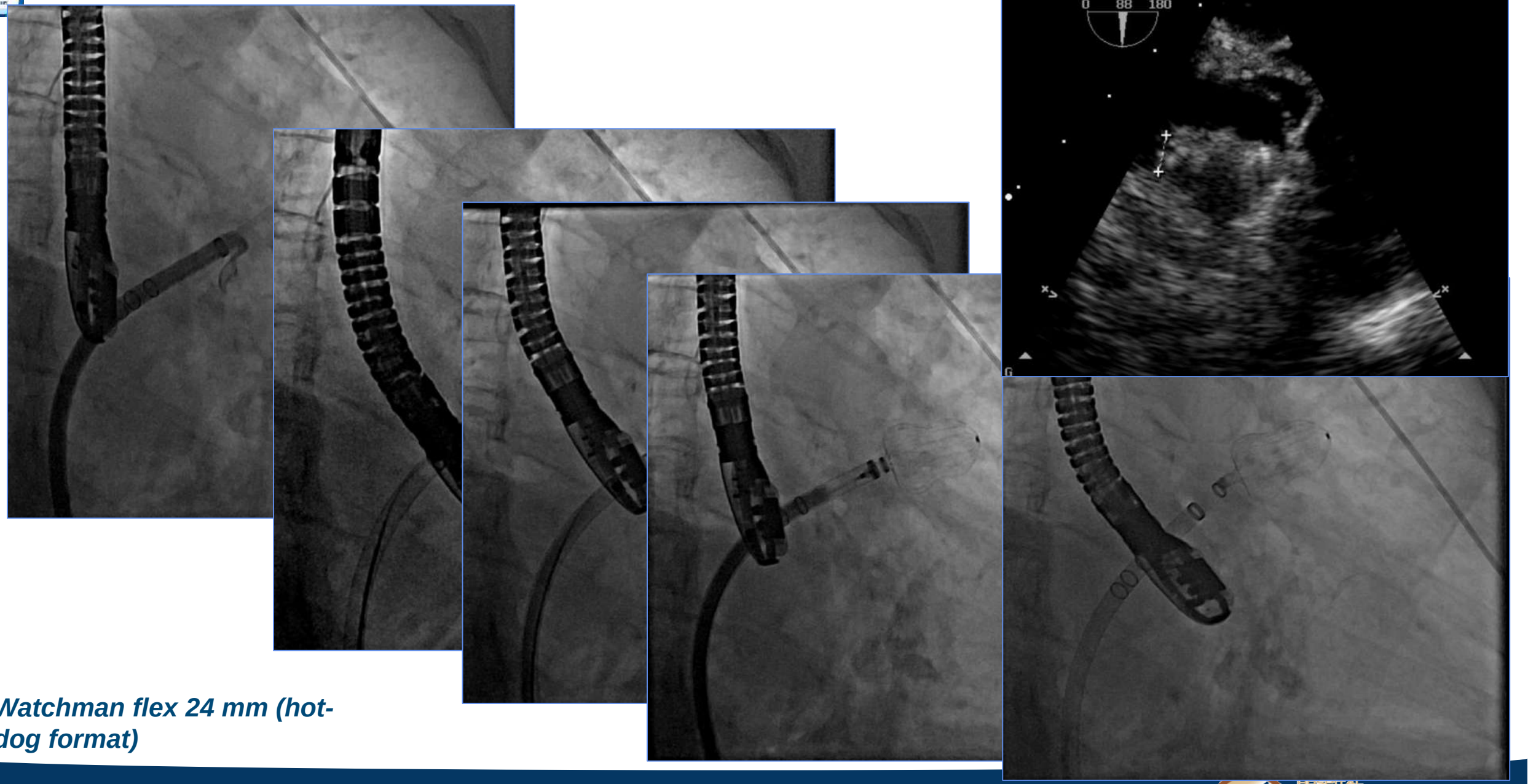






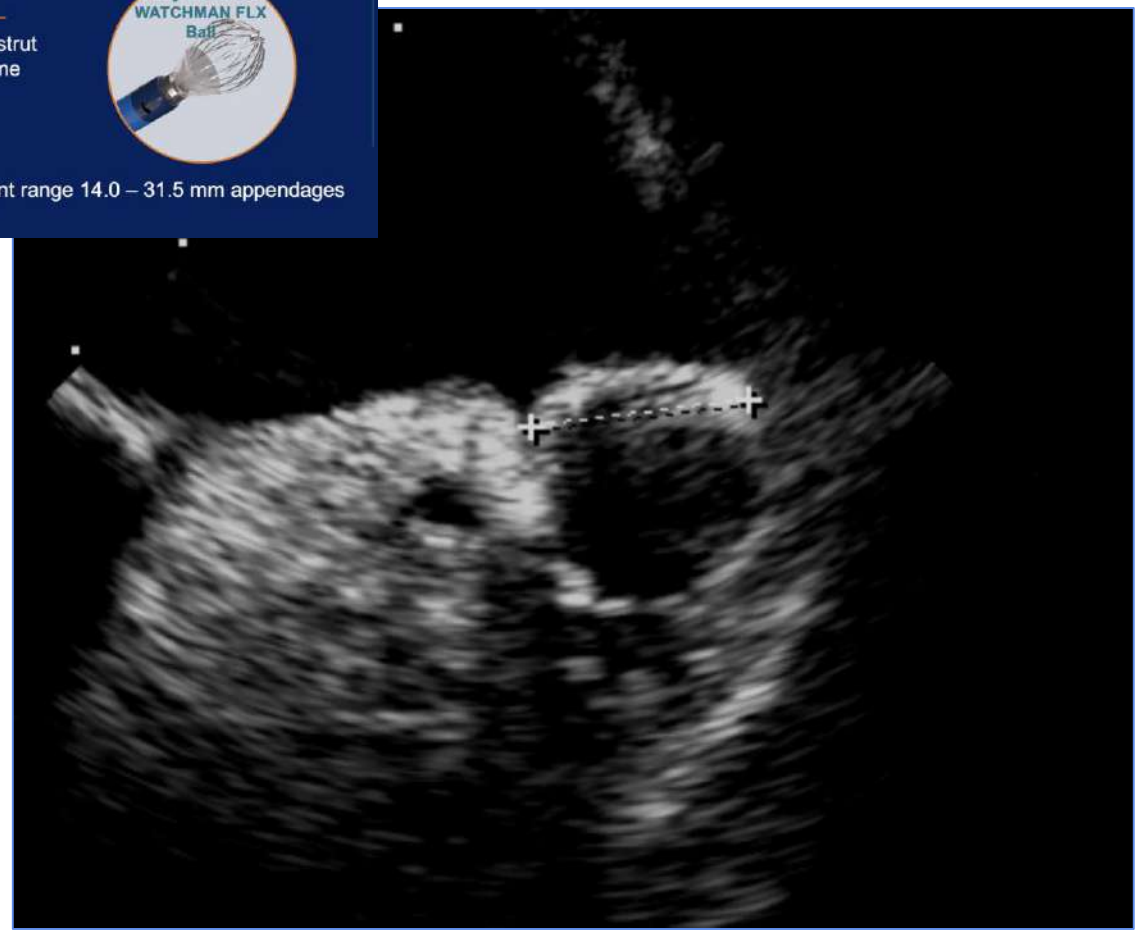


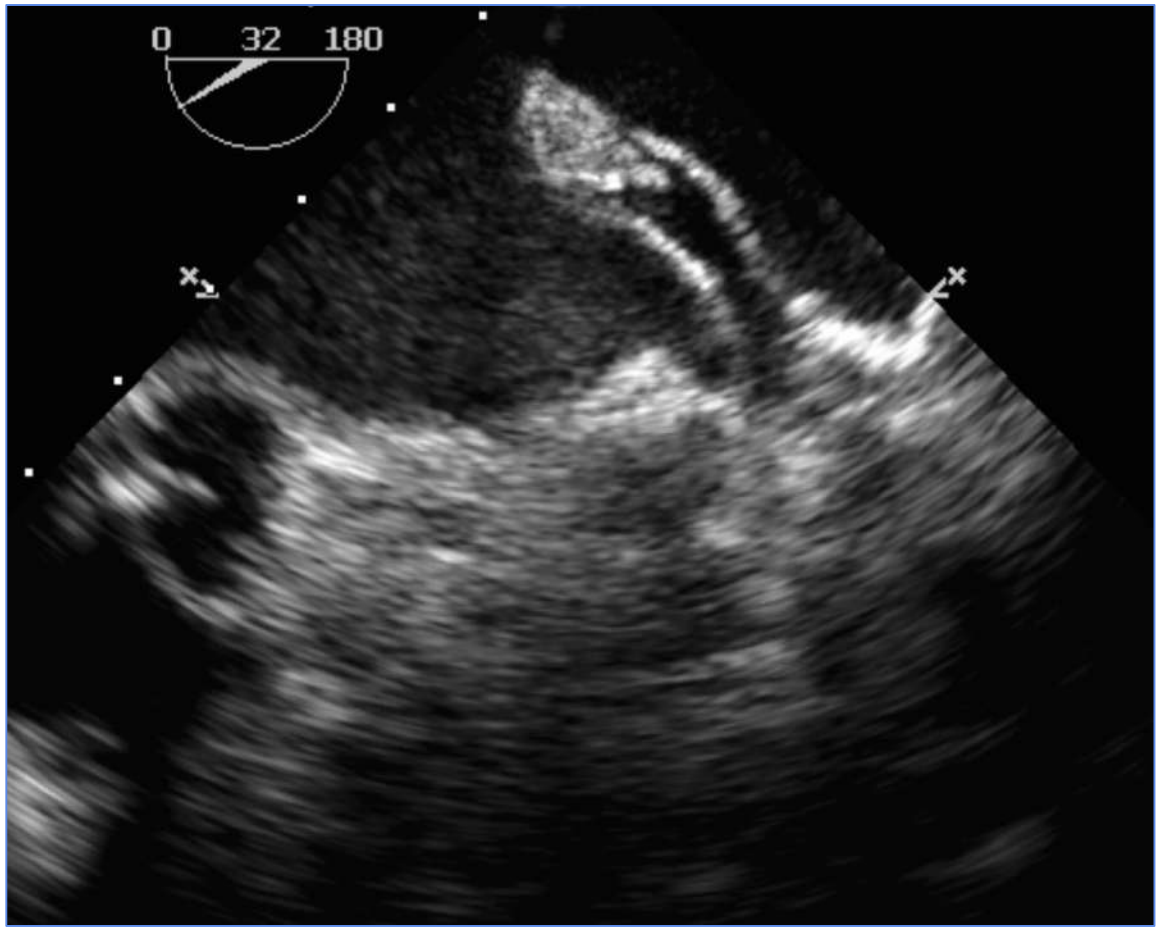
New technology – Watchman Flex Deployment Angiogram



Watchman flex 24 mm (hot-dog format)

TEE assessment – Adequate Device implantation





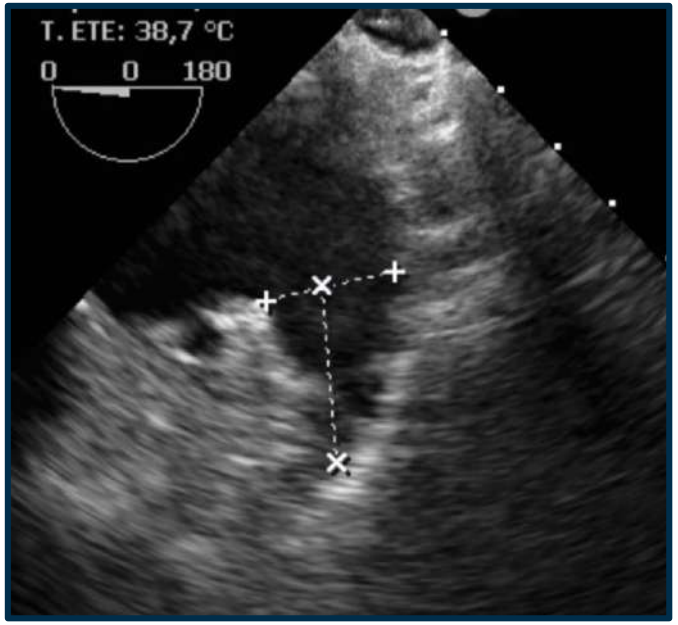
Case # 3

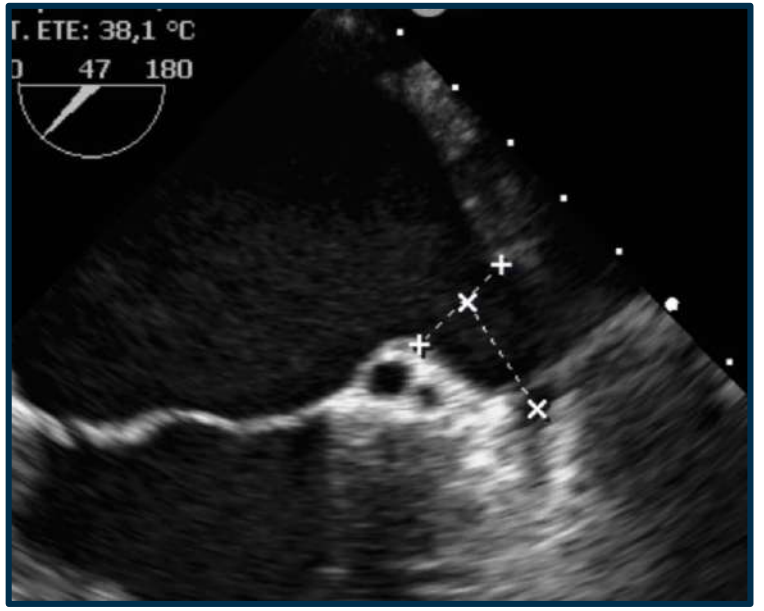
- 78 year-old man
- Main complain: previous hemorrhagic stroke after ischemic acute stroke during anticoagulant therapy
- Non valvular AF, chronic heart failure, LV dysfunction
- Poor adherence to long-term medication

Step 1. TEE anatomy evaluation

Left atrial appendage measurement in 4 views

O=16mm
L=22mm

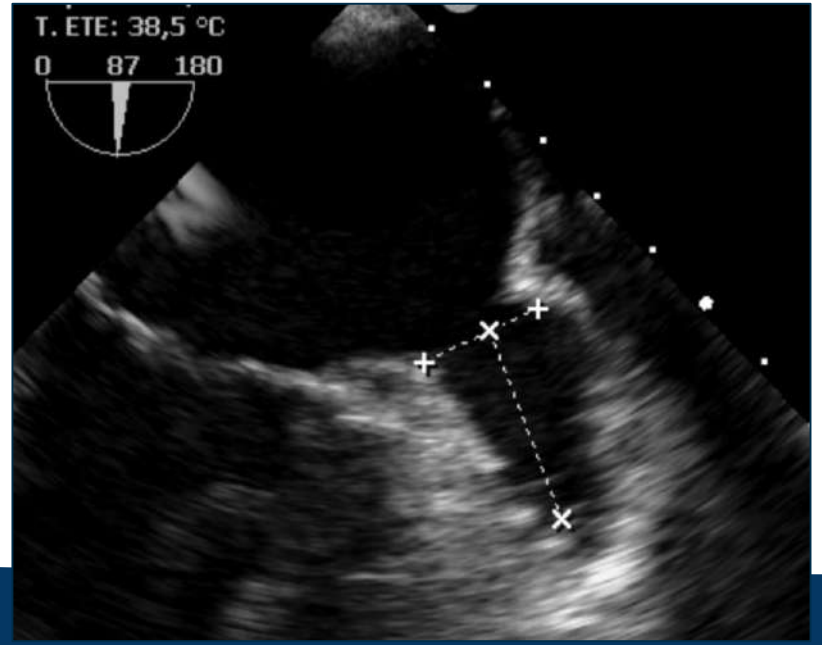


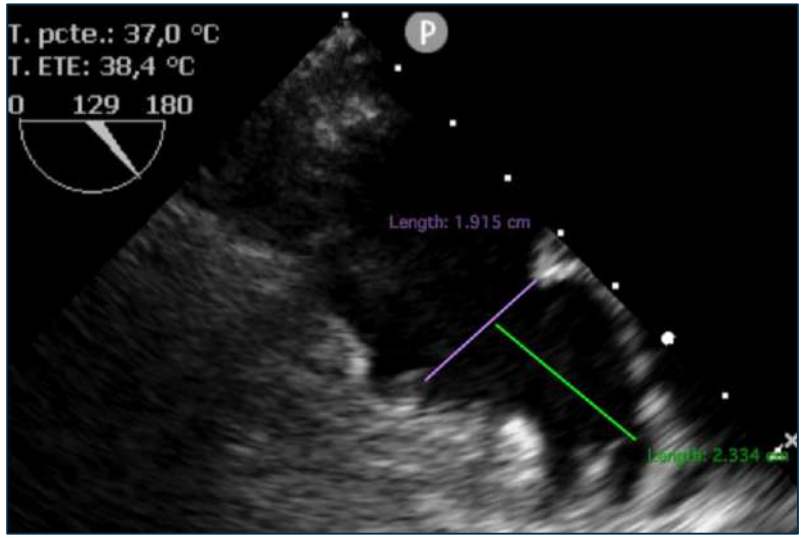


O=14mm
L=17mm

Anatomic challenge: ***Small entrance orifice***

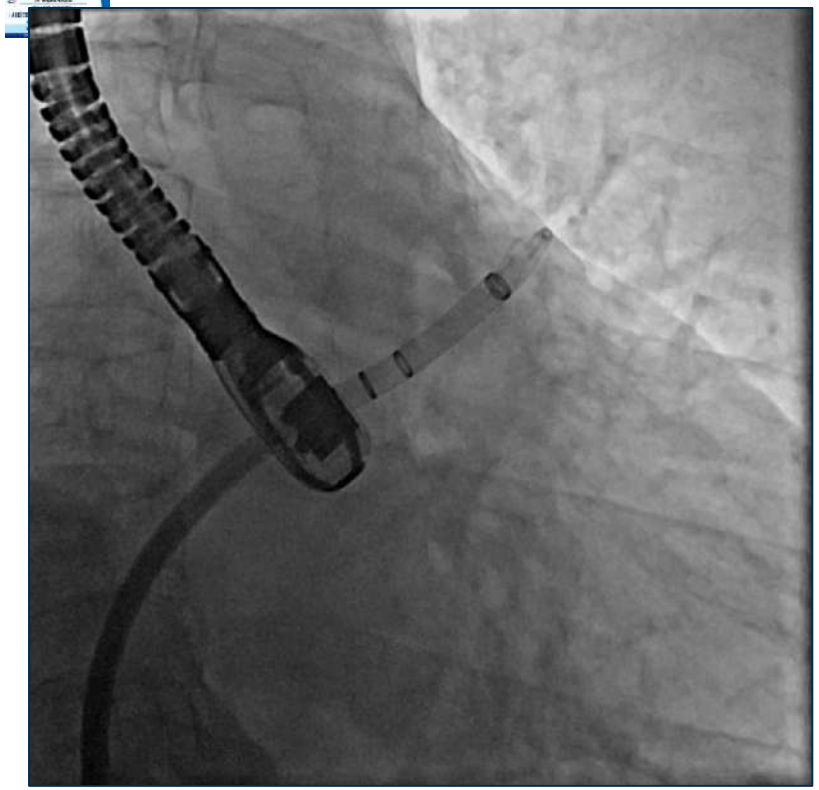
O=16mm
L=25mm

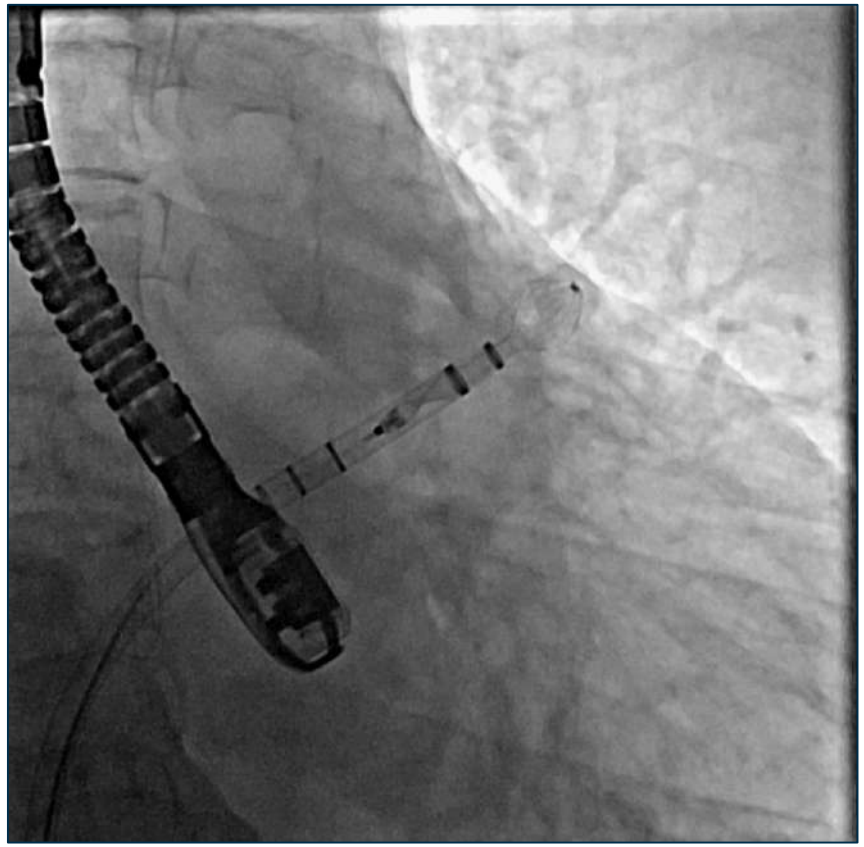


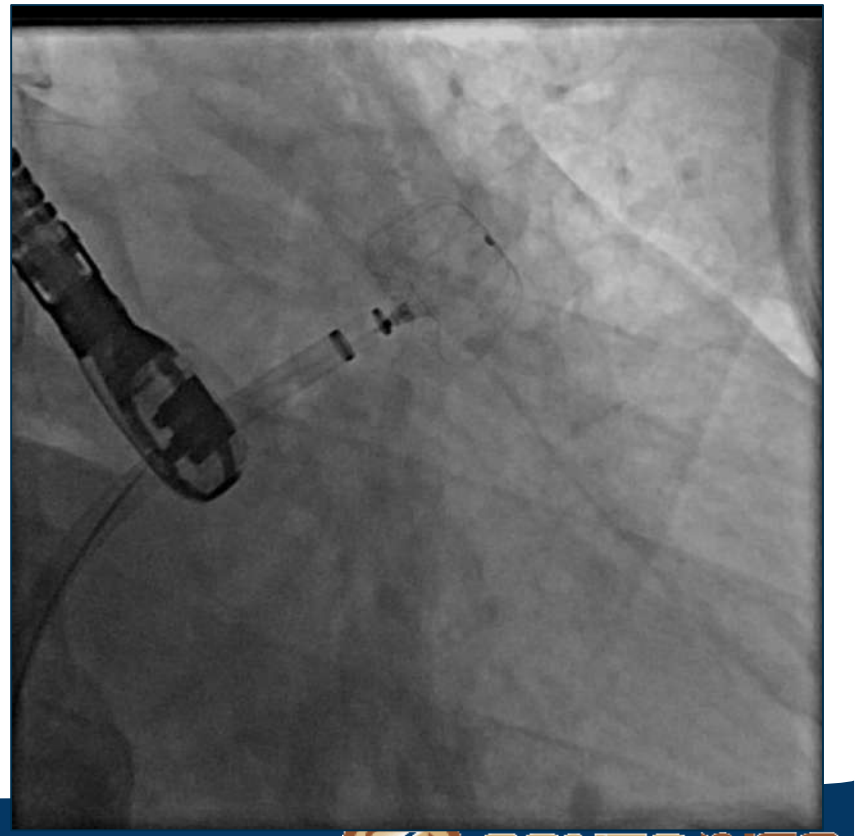


O=18mm
L=23mm

New technology – Watchman Flex 24 mm

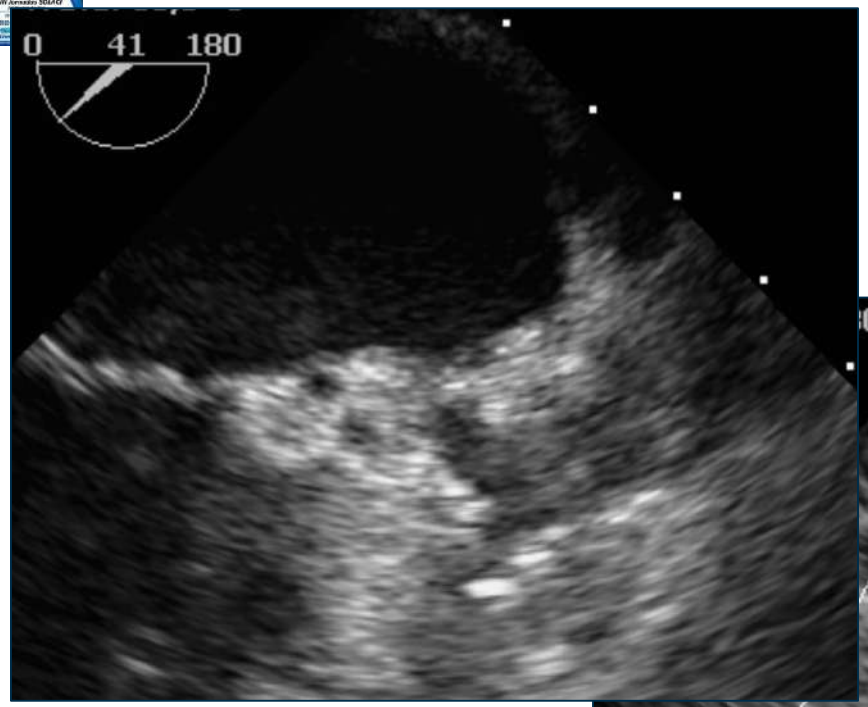


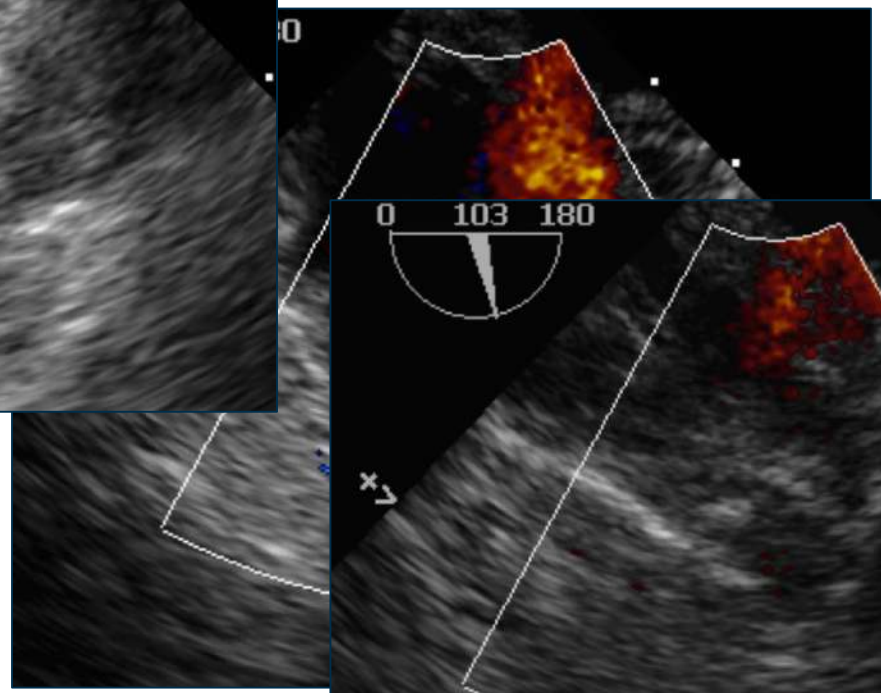


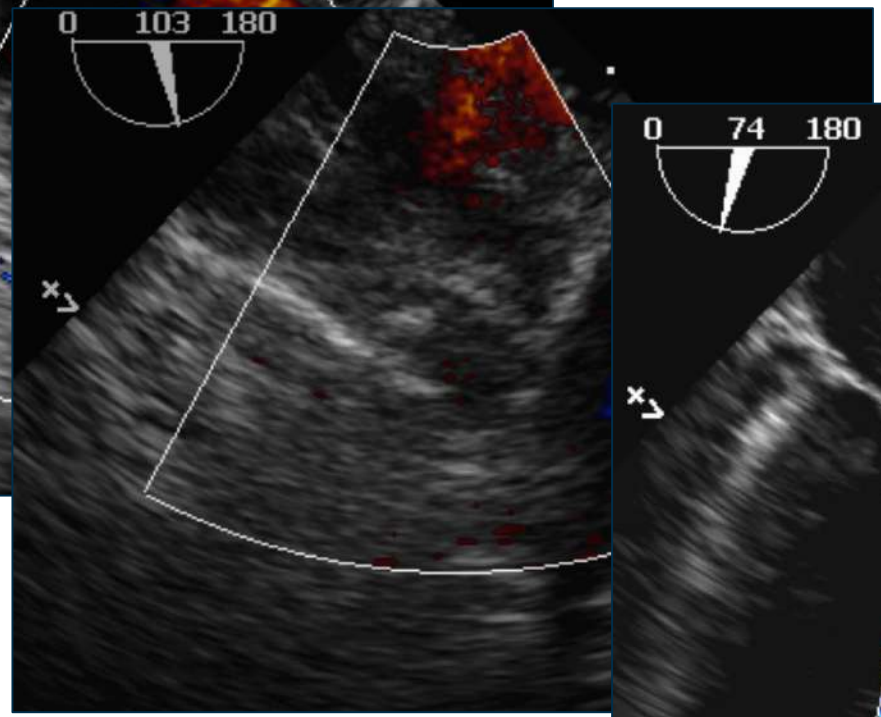


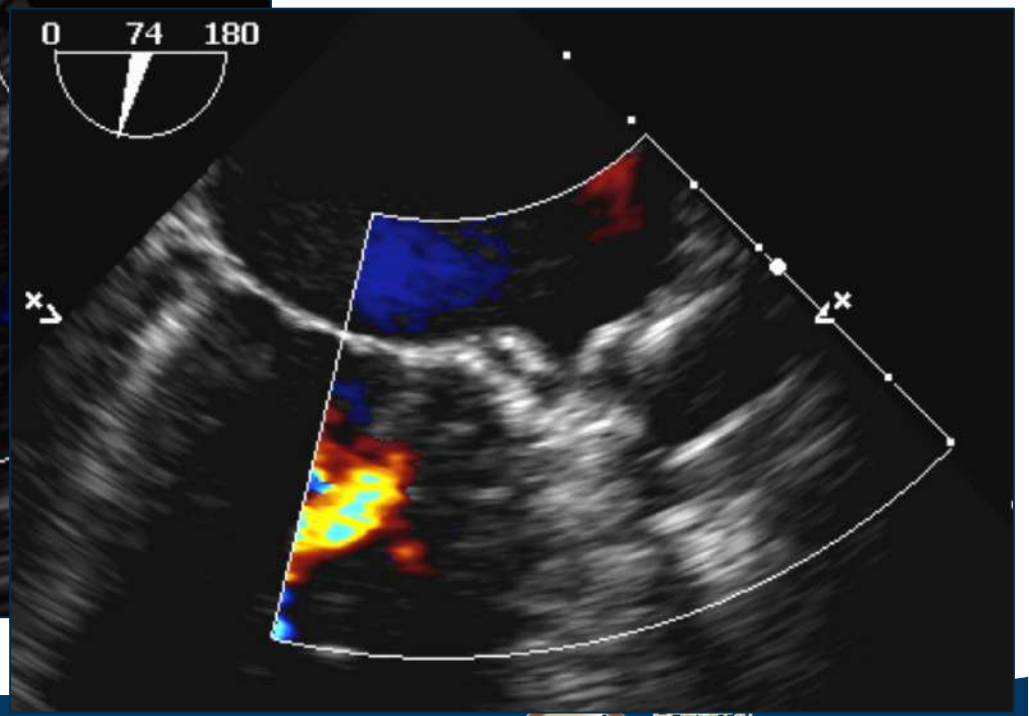
Watchman flex 24 mm
(marshmallow format)

TEE assessment – Adequate Device implantation









Conclusion

- Watchman flex has provided better technical approach
- Most anatomies can be manage with the new system
- Studies has shown similar outcomes relative to W2