LAA Closure in 2024
– Updates and Evolving Techniques

TCTAP 2024

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HKU Med

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Updates in Trials & Guidelines

suboptimal candidates for long-term OAC. CMS also added requirements applied across a range of new technologies, including obligatory registry enrollment and documentation of evidence-based shared decision making with a nonimplanting physician. The National Cardiovascular Data Registry (NCDR) LAA Occlusion (LAAO) Registry reports prior clinical bleeding in almost 70% of patients undergoing LAAC, intracranial bleeding in nearly 12% (vs none in RCTs), and

2019

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]

Physician and institutional requirements

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

The SCAI/ACC/Heart Rhythm Society (HRS) LAAC institutional and operator requirements were published in 2015,[29,30] which

2020

Table 3. 2020 European Society of Cardiology Guidelines for the management of atrial fibrillation.

Recommendations for occlusion or exclusion of the LAA	Class of recommendation	Level of evidence
LAA occlusion may be considered for stroke prevention in patients with AF and contraindications for long-term anticoagulant treatment (eg, intracranial bleeding without a 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	C

AF, atrial fibrillation; LAA, left atrial appendage.
Adapted from Hindricks et al.[20]

ESC European Society of Cardiology

Europace (2023) **25**, 1–9
https://doi.org/10.1093/europace/euad067

STATE OF THE ART REVIEW

Leap or lag: left atrial appendage closure and guidelines

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Abstract

Atrial fibrillation (AF) is associated with life-threatening thromboembolism. Most emboli stem from thrombosis in the left atrial appendage (LAA). The current treatment of choice is oral anticoagulants (OACs), but a small proportion of patients cannot take OACs predominantly because of the so-called unacceptable bleeding risks. However, many who initially accept OACs subsequently stop therapy or reduce the OAC treatment to a potentially non-effective dose leaving them exposed to thromboembolic risk.

A relatively simple alternative therapy involves the catheter-based insertion of a LAA closure (LAAC) device to prevent thromboembolism from the LAA. There is a considerable evidence base for this therapy consisting of clinical trials and observational data which suggests comparable therapeutic efficacy with a possible small excess of ischaemic strokes.

Although LAAC has been very closely examined by regulators and approved for market release, guidelines from most professional societies give only weak recommendations for use of this device which may be the only known effective therapy available to some at-risk AF patients. Guidance materials from the same societies more enthusiastically endorse LAAC.

Clinical practice is running well ahead of the guidelines because equipoise has been lost by physicians faced with patients for whom they have no other effective therapy. Guideline writers are correct in providing recommendations which are less strong for LAAC than for OACs, for those who are able and willing to take OAC treatment, but for those who are not, a stronger recommendation is needed. But, should the guidelines lag behind or leap ahead of the available evidence?

CLINICAL PRACTICE GUIDELINES

2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

Developed in Collaboration With and Endorsed by the American College of Clinical Pharmacy and the Heart Rhythm Society

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AIM: The "2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation" provides recommendations to guide clinicians in the treatment of patients with atrial fibrillation.

6.5.1. Percutaneous Approaches to Occlude the LAA

Recommendations for Percutaneous Approaches to Occlude the LAA

summarized in the Online Data Supplement.

COR	LOE	Recommendations
2a	B-NR	1. In patients with AF, a moderate to high risk of stroke (CHA_2DS_2-VASc score ≥2), and a contraindication (Table 14) to long-term oral anticoagulation due to a nonreversible cause, percutaneous LAAO (pLAAO) is reasonable.[1-4]
2b	B-R	2. In patients with AF and a moderate to high risk of stroke and a high risk of major bleeding on oral anticoagulation, pLAAO may be a reasonable alternative to oral anticoagulation based on patient preference, with careful consideration of procedural risk and with the understanding that the evidence for oral anticoagulation is more extensive.[1-3,5,6]

Left Atrial Appendage Closure Technology) prospective registry showed a high rate of Watchman device procedural success (98.5%) with a low ischemic stroke risk (1.1%). This low ischemic stroke was demonstrated despite most of the patients (73%) not using oral anticoagulation periprocedurally.[6] The PINNACLE FLX (Protection Against Embolism for Nonvalvular AF Patients: Investigational Device Evaluation of the Watchman FLX LAA Closure Technology) prospective registry of the next-generation Watchman FLX device showed a high rate of procedural success (98.8%) and a low rate (0.5%) of the primary safety endpoint (death, ischemic stroke, systemic embolism, procedure-related events requiring open cardiac

Table 14. Situations in Which Long-Term Anticoagulation Is Contraindicated and Situations When It Remains Reasonable

Long-Term Anticoagulation Contraindicated	Long-Term Anticoagulation Is Still Reasonable
Severe bleeding due to a nonreversible cause involving the gastrointestinal, pulmonary, or genitourinary systems Spontaneous intracranial/intraspinal bleeding due to a nonreversible cause Serious bleeding related to recurrent falls when cause of falls is not felt to be treatable	Bleeding involving the gastrointestinal, pulmonary, or genitourinary systems that is treatable Bleeding related to isolated trauma Bleeding related to procedural complications

surgery or major endovascular intervention).[7]

rates of major bleeding compared with warfarin.[3] PRAGUE-17 (Left Atrial Appendage Closure vs Novel Anticoagulation Agents in Atrial Fibrillation) was an RCT that compared pLAAO with DOACs in patients with nonvalvular AF.[4] pLAAO was noninferior to DOACs for the combined safety and efficacy composite endpoint (stroke, TIA, systemic embolism, cardiovascular death, major or nonmajor clinically relevant bleeding, or procedure-/device-related complications).

6.5.2. Cardiac Surgery—LAA Exclusion/Excision

Recommendations for Cardiac Surgery—LAA Exclusion/Excision		
Referenced studies that support the recommendations are summarized in the Online Data Supplement.		

Joglar JA, Chung MK, Armbruster AL, Benjamin EJ, Chyou JY, Cronin EM, Deswal A, Eckhardt LL, Goldberger ZD, Gopinathannair R, Gorenek B, Hess PL, Hlatky M, Hogan G, Ibeh C, Indik JH, Kido K, Kusumoto F, Link MS, Linta KT, Marcus GM, McCarthy PM, Patel N, Patton KK, Perez MV, Piccini JP, Russo AM, Sanders P, Streur MM, Thomas KL, Times S, Tisdale JE, Valente AM, Van Wagoner DR. 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2024 Jan 2;149(1):e1-e156. doi: 10.1161/CIR.0000000000001193. Epub 2023 Nov 30. Erratum in: Circulation. 2024 Jan 2;149(1):e167. Erratum in: Circulation. 2024 Feb 27;149(9):e936. PMID: 38033089.

3 Year Outcome AMULET IDE

3-Year Outcomes from the Amplatzer™ Amulet™ Left Atrial Appendage Occluder Randomized Controlled Trial (Amulet IDE)

Dhanunjaya Lakkireddy
David Thaler, Christopher R. Ellis, Vijendra Swarup, Alok Gambhir, James Hermiller, Jens Erik Nielsen-Kudsk, Stephen Worthley, Devi Nair, Boris Schmidt, Mohamad Alkhouli, Rodney Horton, Nigel Gupta, Stephan Windecker

PLAGUE-17 4 Year Results

4-Year Outcomes After Left Atrial Appendage Closure Versus Nonwarfarin Oral Anticoagulation for Atrial Fibrillation

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ABSTRACT

BACKGROUND The PRAGUE-17 (Left Atrial Appendage Closure vs Novel Anticoagulation Agents in Atrial Fibrillation) trial demonstrated that left atrial appendage closure (LAAC) was noninferior to nonwarfarin direct oral anticoagulants (DOACs) for preventing major neurological, cardiovascular, or bleeding events in patients with atrial fibrillation (AF) who were at high risk.

OBJECTIVES This study sought to assess the prespecified long-term (4-year) outcomes in PRAGUE-17.

METHODS PRAGUE-17 was a randomized noninferiority trial comparing percutaneous LAAC (Watchman or Amulet) with DOACs (95% apixaban) in patients with nonvalvular AF and with a history of cardioembolism, clinically-relevant bleeding, or both CHA_2DS_2-VASc ≥3 and HASBLED ≥2. The primary endpoint was a composite of cardioembolic events (stroke, transient ischemic attack, or systemic embolism), cardiovascular death, clinically relevant bleeding, or procedure-/device-related complications (LAAC group only). The primary analysis was modified intention-to-treat.

RESULTS This study randomized 402 patients with AF (201 per group, age 73.3 ± 7.0 years, 65.7% male, CHA_2DS_2-VASc 4.7 ±1.5, HASBLED 3.1 ± 0.9). After 3.5 years median follow-up (1,354 patient-years), LAAC was noninferior to DOACs for the primary endpoint by modified intention-to-treat (subdistribution HR [sHR]: 0.81; 95% CI: 0.56-1.18; $P = 0.27$; P for noninferiority = 0.006). For the components of the composite endpoint, the corresponding sHRs were 0.68 (95% CI: 0.39-1.20; $P = 0.19$) for cardiovascular death, 1.14 (95% CI: 0.56-2.30; $P = 0.72$) for all-stroke/transient ischemic attack, 0.75 (95% CI: 0.44-1.27; $P = 0.28$) for clinically relevant bleeding, and 0.55 (95% CI: 0.31-0.97; $P = 0.039$) for nonprocedural clinically relevant bleeding. The primary endpoint outcomes were similar in the per-protocol (sHR: 0.80; 95% CI: 0.54-1.18; $P = 0.25$) and on-treatment (sHR: 0.82; 95% CI: 0.56-1.20; $P = 0.30$) analyses.

CONCLUSIONS In long-term follow-up of PRAGUE-17, LAAC remains noninferior to DOACs for preventing major cardiovascular, neurological, or bleeding events. Furthermore, nonprocedural bleeding was significantly reduced with LAAC. (PRAGUE-17 [Left Atrial Appendage Closure vs Novel Anticoagulation Agents in Atrial Fibrillation]; NCT02426944)
(J Am Coll Cardiol 2022;79:1-14)

PINNACLE FLX – 2 Year Outcome

BRIEF COMMUNICATION

Two-Year Outcomes With a Next-Generation Left Atrial Appendage Device: Final Results of the PINNACLE FLX Trial

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BACKGROUND: The PINNACLE FLX (Protection Against Embolism for Non-valvular AF [Atrial Fibrillation] Patients: Investigational Device Evaluation of the Watchman FLX LAA [Left Atrial Appendage] Closure Technology) trial evaluated the safety and efficacy of a next-generation left atrial appendage closure device (WATCHMAN FLX; Boston Scientific, Marlborough, MA). At 1 year, the study met the primary end points of safety and anatomical efficacy/appendage closure. This final report of the PINNACLE FLX trial includes the prespecified secondary end point of ischemic stroke or systemic embolism at 2 years, also making it the first report of 2-year outcomes with this next-generation left atrial appendage closure device.

METHODS AND RESULTS: Patients with nonvalvular atrial fibrillation with CHA_2DS_2-VASc score ≥2 (men) or ≥3 (women), with an appropriate rationale for left atrial appendage closure, were enrolled to receive the left atrial appendage closure device at 29 US centers. Adverse events were assessed by an independent clinical events committee, and imaging was assessed by independent core laboratories. Among 395 implanted patients (36% women; mean age, 74 years; CHA_2DS_2-VASc, 4.2±1.5), the secondary efficacy end point of 2-year ischemic stroke or systemic embolism was met, with an absolute rate of 3.4% (annualized rate, 1.7%) and an upper 1-sided 95% confidence bound of 5.3%, which was superior to the 8.7% performance goal. Two-year rates of adverse events were as follows: 9.3% all-cause mortality, 5.5% cardiovascular death, 3.4% all stroke, and 10.1% major bleeding (Bleeding Academic Research Consortium 3 or 5). There were no additional systemic embolisms, device embolizations, pericardial effusions, or symptomatic device-related thrombi after 1 year.

CONCLUSIONS: The secondary end point of 2-year stroke or systemic embolism was met at 3.4%. In these final results of the PINNACLE FLX trial, the next-generation WATCHMAN FLX device demonstrated favorable safety and efficacy outcomes.

REGISTRATION: URL: https://www.clinicaltrials.gov; Unique identifier: NCT02702271.

Key Words: atrial fibrillation ■ left atrial appendage closure ■ WATCHMAN FLX

PINNACLE FLX

PINNACLE FLX, the **WATCHMAN FLX™ Left Atrial Appendage Closure Device** US IDE Trial, demonstrated **unmatched 0.5% major adverse event rate, 100% Effective LAA Closure,** and a low **1.7% Annualized Ischemic Stroke or Systemic Embolism rate** at 24 months.[1, 2]

View Full 12-Month Results

View Full 24-Month Results

1 Kar S., Circulation, 2021.
2 Doshi et al. JAHA, 2023.

Impact of Peridevice Leak on 5-Year Outcomes After Left Atrial Appendage Closure

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ABSTRACT

BACKGROUND In the U.S. Food and Drug Administration (FDA) clinical trials of left atrial appendage (LAA) closure, a postimplantation peridevice leak (PDL) of ≤5 mm (PDL≤5) was accepted as sufficient LAA "closure." However, the clinical consequences of these PDLs on subsequent thromboembolism are poorly characterized.

OBJECTIVES We sought to assess the impact of PDL≤5 on clinical outcomes after implantation of the Watchman device.

METHODS Using combined data from the FDA studies PROTECT-AF (Watchman Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation), PREVAIL (Evaluation of the Watchman Left Atrial Appendage Closure Device in Patients With Atrial Fibrillation vs Long Term Warfarin Therapy), and CAP2 (Continued Access to PREVAIL), we assessed patients with successful device implantation for PDL by means of protocol-mandated transesophageal echocardiograms (TEEs) at 45 days and 1 year. Five-year outcomes were assessed as a function of the absence or presence of PDL≤5.

RESULTS The cohort included 1,054 patients: mean age 74 ± 8.3 years, 65% male, and CHA_2DS_2-VASc 4.1 ± 1.4. TEE imaging at 45 days revealed 634 patients (60.2%) without and 404 (38.3%) with PDL≤5, and 1-year TEE revealed 704 patients (71.6%) without and 272 (27.7%) with PDL≤5. The presence of PDL≤5 at 1 year, but not at 45 days, was associated with an increased 5-year risk of ischemic stroke or systemic embolism (adjusted HR: 1.94; 95% CI: 1.15-3.29; $P = 0.014$), largely driven by an increase in nondisabling stroke (HR: 1.97; 95% CI: 1.03-3.78; $P = 0.04$), while disabling or fatal stroke rates were similar (HR: 0.69; 95% CI: 0.19-2.46; $P = 0.56$). PDL≤5 was not associated with an increased risk of cardiovascular or unexplained death (HR: 1.20; $P = 0.45$) or all-cause death (HR: 0.87; $P = 0.42$).

Study Design

Retrospective, post-hoc analysis of the Legacy WATCHMAN™ Left Atrial Appendage Closure Device using the PROTECT-AF, PREVAIL studies and CAP2 registry data.[1]

Assessment of peri-device leak (PDL) impact at 45 days and 12 months on long-term ischemic stroke or systemic embolism outcomes.

Peri-device leak from pooled patient data was categorized at 45 days and 1-year based on:

- Severity of leak (0mm vs >0-3mm vs >3-5mm vs >5mm)
- No leak vs any leak (>0mm to 5mm)

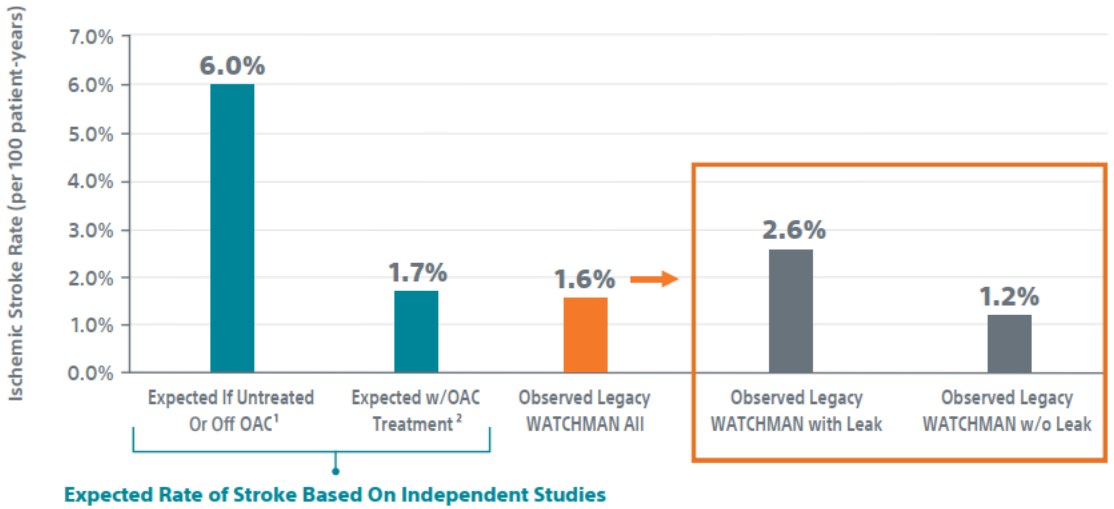
1 Presented at AHA, 2021, Vivek Reddy, M.D.
CAP-1 was not included because leak assessment was not consistently captured.
>5mm leaks were excluded from this analysis as larger leaks are established as associated with adverse outcomes.

SH-1553805-AB

Study Outcome

There was meaningful stroke reduction at 5 years in patients with and without leak, with a combined annualized risk of 1.6% per year versus an expected ~6% risk for untreated patients.*[3]

Expected vs Observed Ischemic Stroke Rate for Leak



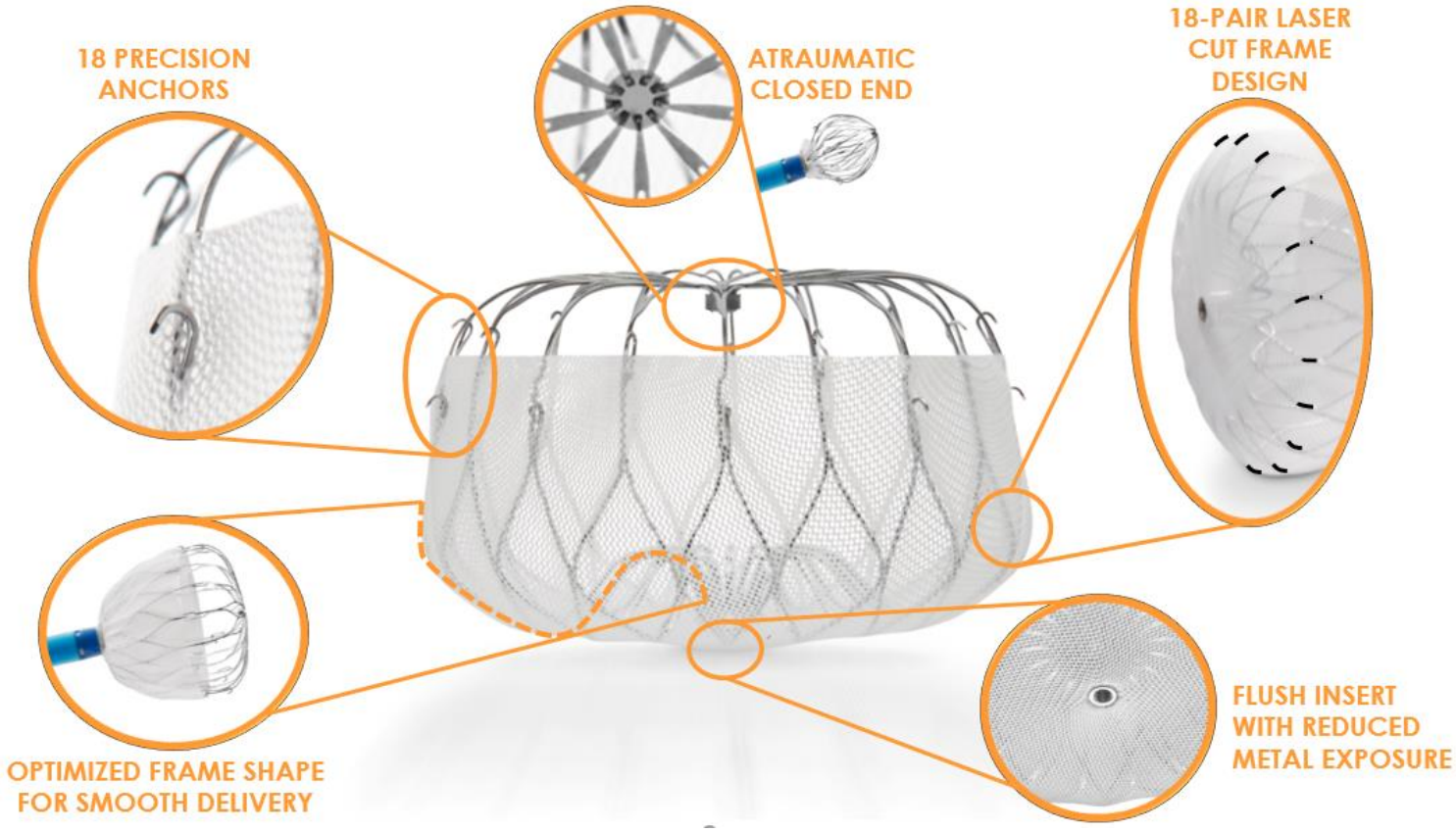
- There was no association between leak at 45 days and long-term outcomes (similar to findings from the previous published PROTECT-AF study)
- Peri-device leak at 1-year was associated with an increased risk of ischemic stroke or systemic embolism with the Legacy WATCHMAN™ Left Atrial Appendage Closure Device

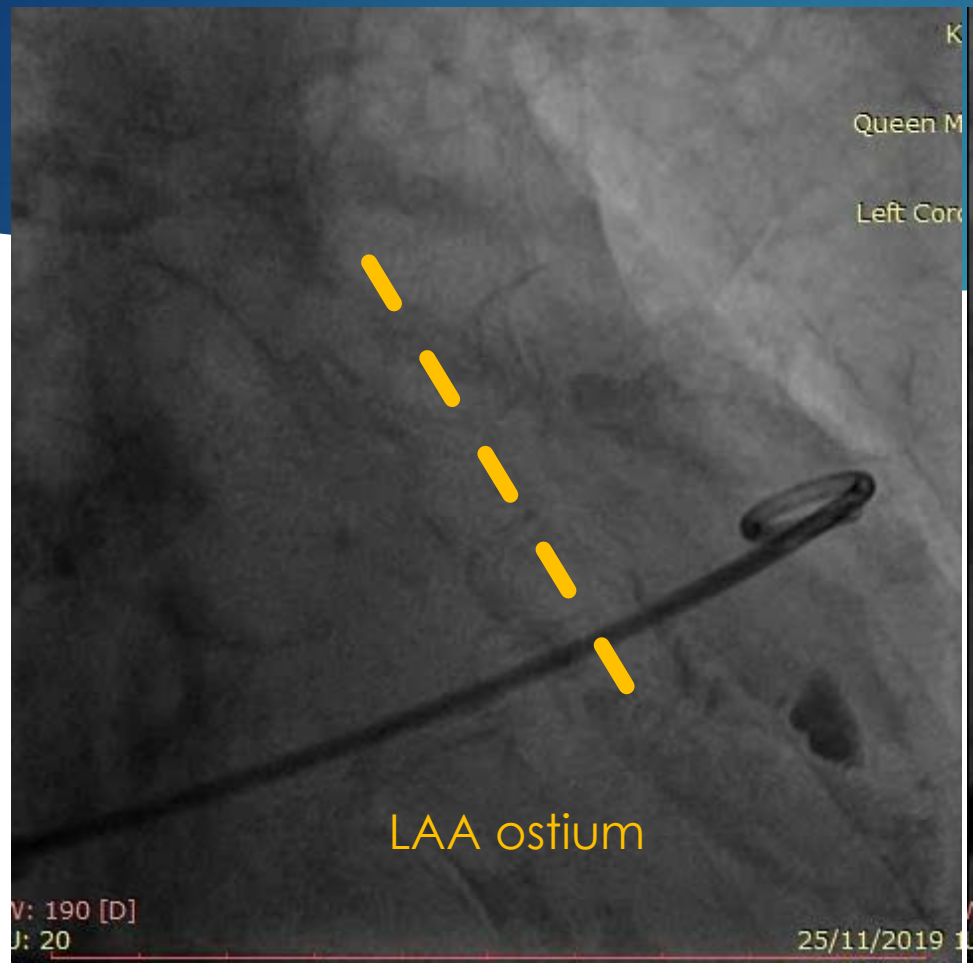
*Expected annualized rate of ischemic stroke for a patient population with identical baseline CHADSVASC score.

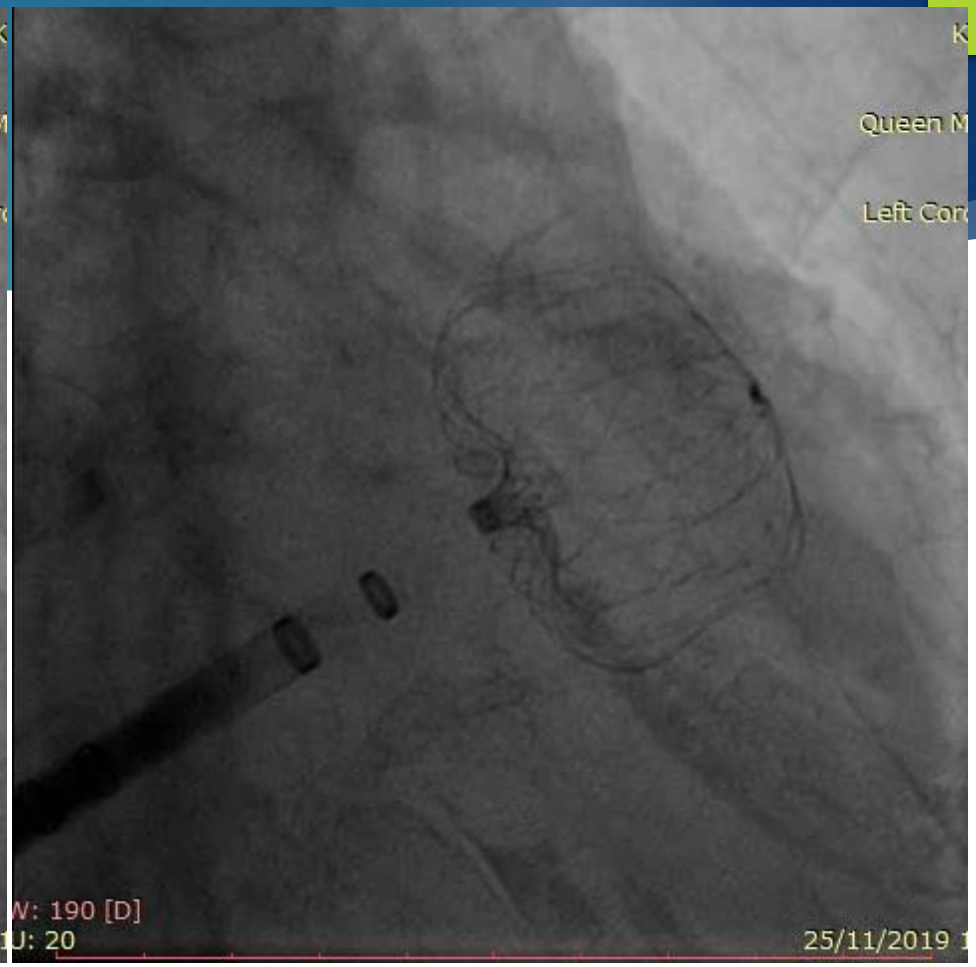
1 Freiberg et al. European Heart Journal (2012) 33, 1500–1510.
2 Oleson et al. Thromb Haemost 2011; 106: 739–749.
3 Presented at AHA, 2021, Vivek Reddy, M.D.

Latest Commonly Used LAAO Devices

WATCHMAN FLX

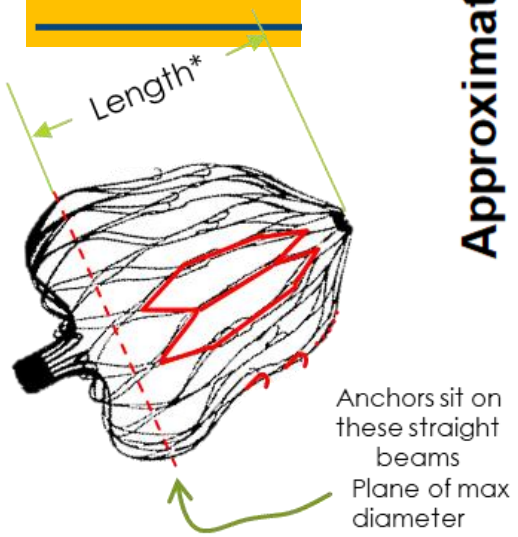

18 PRECISION ANCHORS
ATRAUMATIC CLOSED END
18-PAIR LASER CUT FRAME DESIGN
OPTIMIZED FRAME SHAPE FOR SMOOTH DELIVERY
FLUSH INSERT WITH REDUCED METAL EXPOSURE

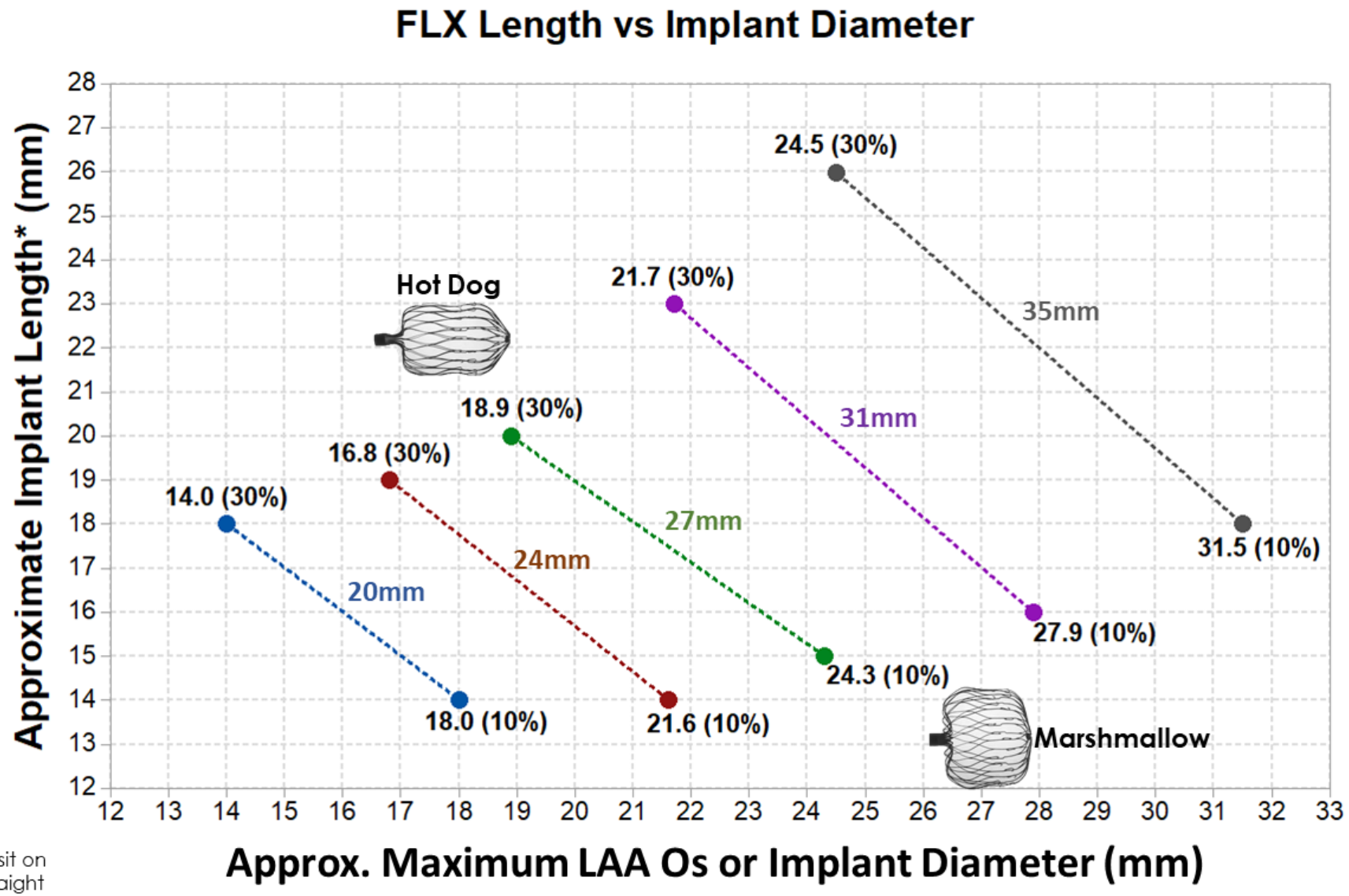




WATCHMAN FLX 35mm


Marshmallow
Bell
Hot-Dog


Length*
Anchors sit on these straight beams
Plane of max diameter


FLX Length vs Implant Diameter
Approximate Implant Length* (mm)
Approx. Maximum LAA Os or Implant Diameter (mm)
Hot Dog
Marshmallow
24.5 (30%)
21.7 (30%)
18.9 (30%)
16.8 (30%)
14.0 (30%)
35mm
31mm
27mm
24mm
20mm
31.5 (10%)
27.9 (10%)
24.3 (10%)
21.6 (10%)
18.0 (10%)

WATCHMAN FLX PRO

WATCHMAN FLX Pro Design Goals

Built on the proven safety profile of WATCHMAN FLX,
WATCHMAN FLX Pro is designed to optimize the therapy for more patients.

Boston Scientific

WATCHMAN FLX™ Pro

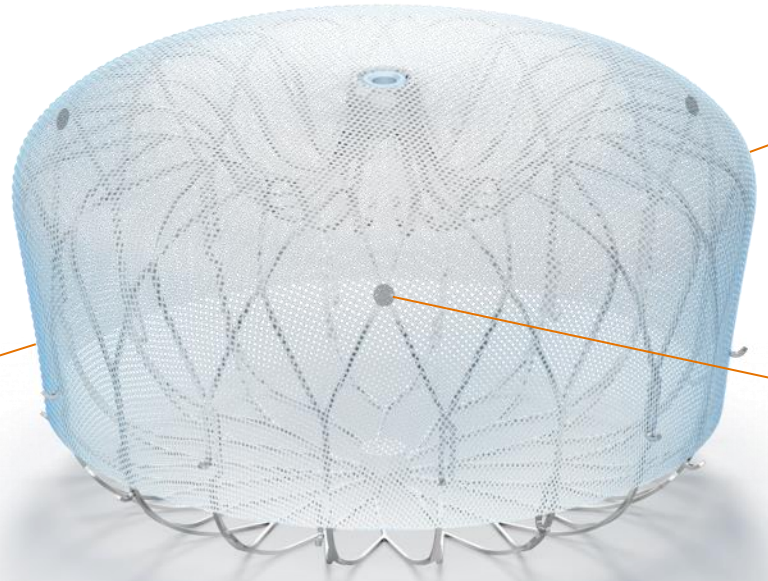
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

WATCHMAN FLX platform

with proven safety & procedural performance[1]

New 40mm device

to treat even larger anatomies



HEMOCOAT™ Technology

to promote faster, more complete endothelialization

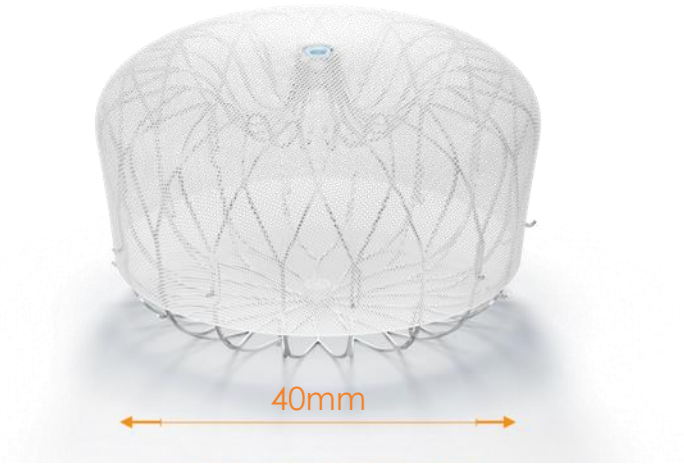
New radiopaque markers

help position and anchor device with a new level of visual accuracy

WATCHMAN FLX Pro is designed to enhance the healing process and optimize LAAC for more patients

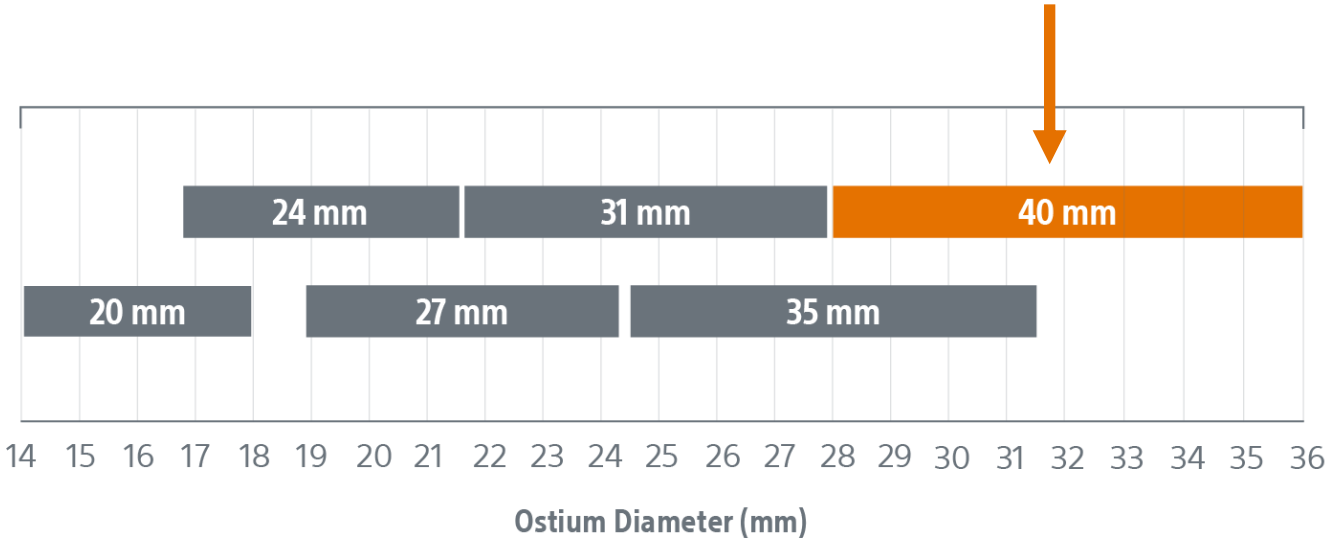
New 40mm Device Designed to Better Treat More Patients with Larger LAAs

New 40mm device



- Same Performance[1]
- Same Compression Range (10-30%)[1]
- Same Depth Requirement[1]

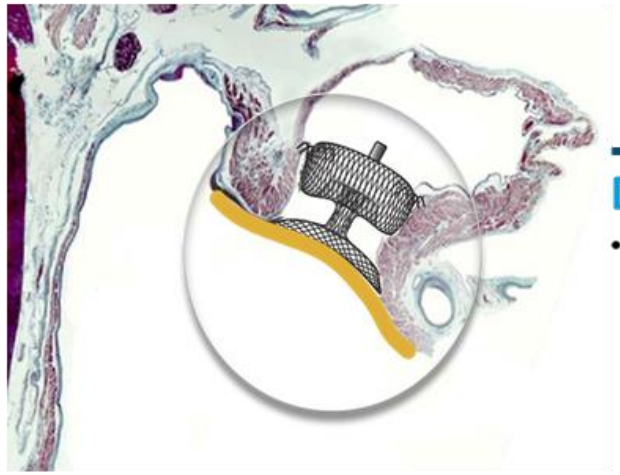
25% Larger Size Range



AMULET

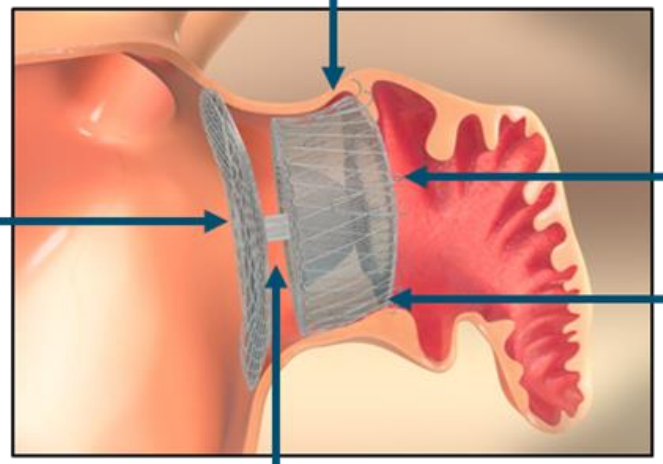
Abbott AMULET

Left Atrial Appendage Occlusion Device



Disc

- Designed to **completely seal** the LAA at the orifice



Lobe

- Positioned **inside** the LAA neck
- Designed **to conform** to different sizes and shapes of LAA anatomy

Stabilizing Wires

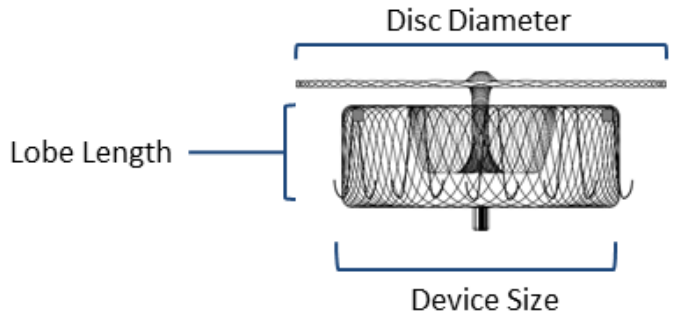
- **Engage** with the wall of the LAA
- **Help** hold the device in place

Waist

- **Maintains tension** between lobe and disc
- **Flexible connection** allows device to self-orient

Device Size Selection - Amulet

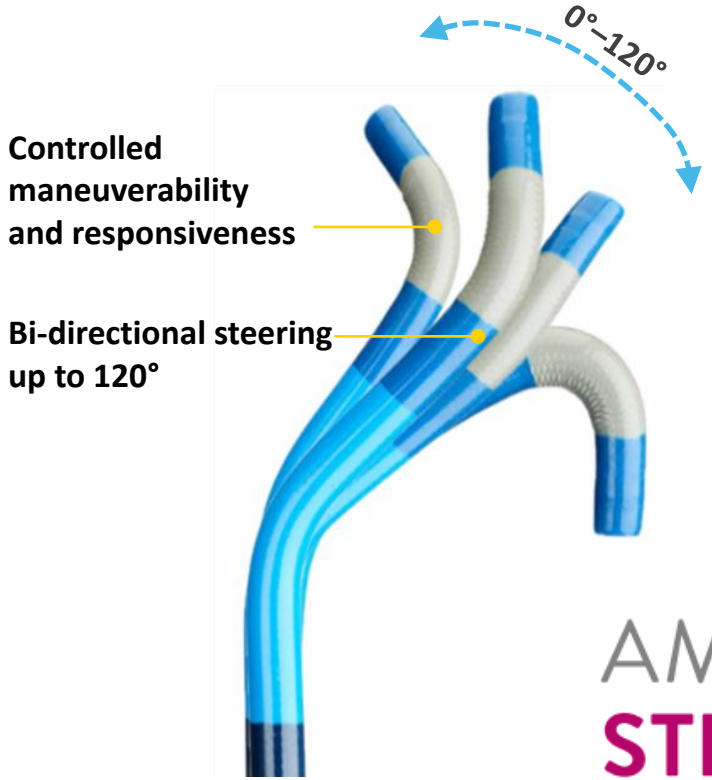
Maximum Landing Zone Width (mm)	Amulet™ Device Size	Lobe Length (mm)	Minimum LAA Depth (mm)	Disc Diameter (mm)	Sheath Diameter
11.0-13.0	**16**	7.5	≥ 10	22	12 F *or* 14 F (with adaptor)
13.0-15.0	**18**	7.5	≥ 10	24	
15.0-17.0	**20**	7.5	≥ 10	26	
17.0-19.0	**22**	7.5	≥ 10	28	
19.0-22.0	**25**	10	≥ 12	32	
22.0-25.0	**28**	10	≥ 12	35	14 F
25.0-28.0	**31**	10	≥ 12	38	
28.0-31.0	**34**	10	≥ 12	41	



AMULET™ STEERABLE DELIVERY SHEATH

Successful Closure Starts with Precise Placement

ADDS PRECISION AND PREDICTABILITY TO IMPLANTING IN ANY LAA ANATOMY



Features bi-directional steering that optimizes precise coaxial alignment of the Amplatzer™ Amulet™ lobe in the landing zone and the disc at the ostium

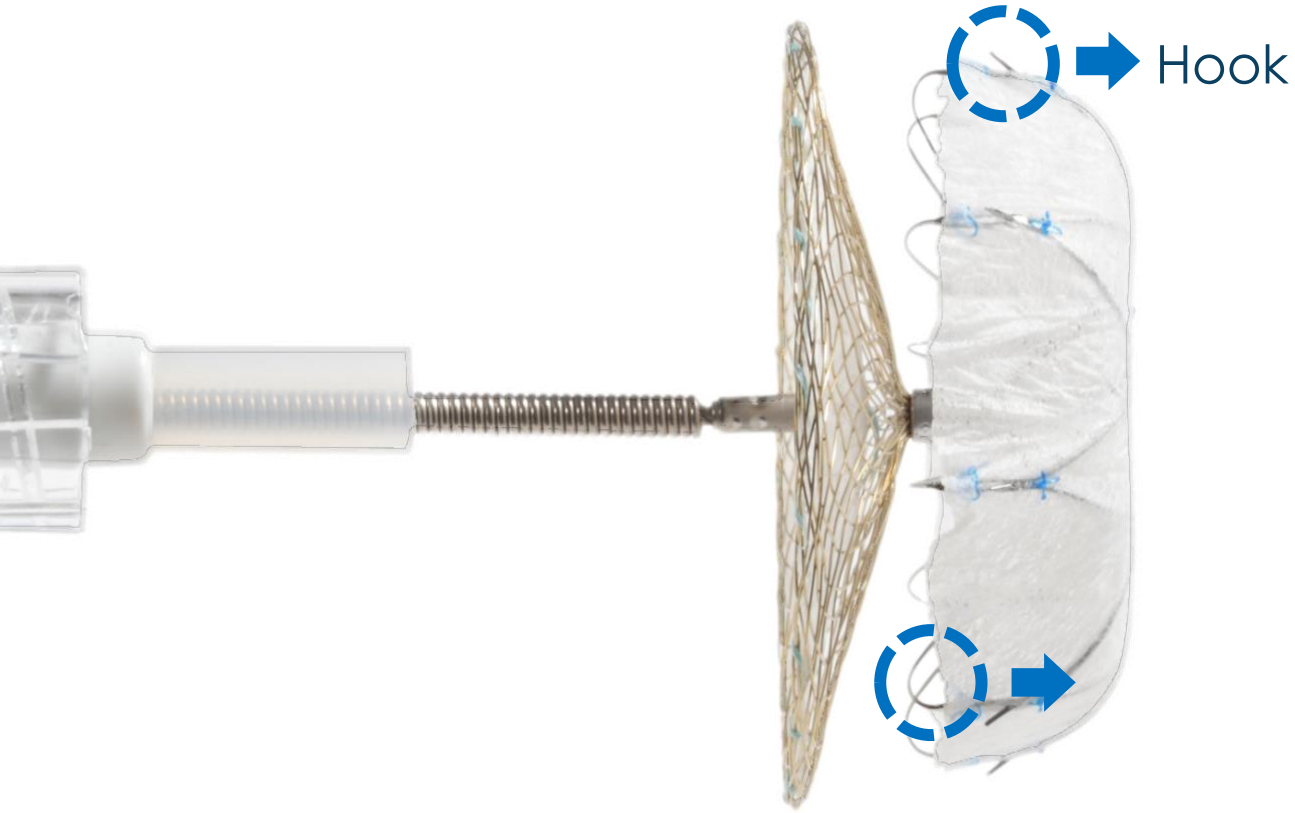
AMPLATZER™
STEERABLE
DELIVERY SHEATH

FOR IMPLANTING THE AMPLATZER™ AMULET™
LEFT ATRIAL APPENDAGE OCCLUDER DEVICE

LAmbre

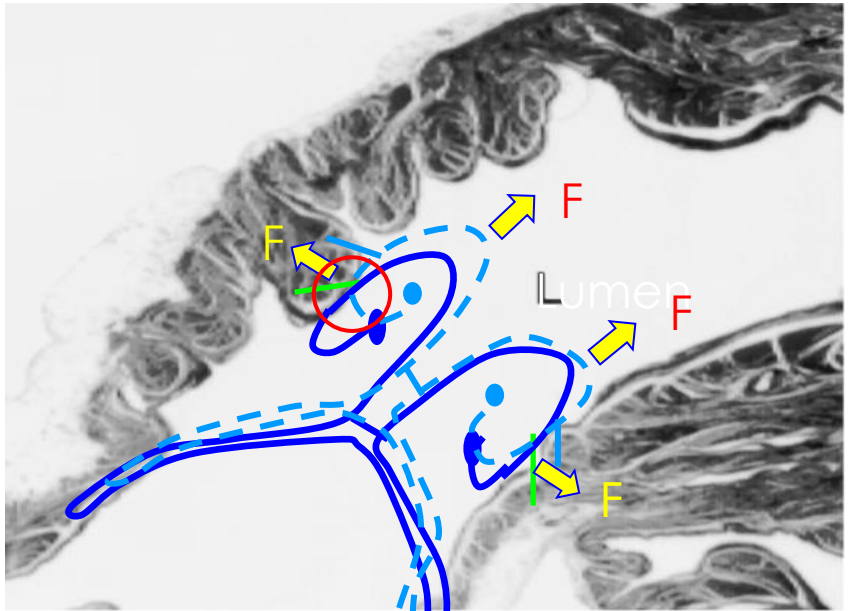
Stable Device Fixation

Patented Anchor Design

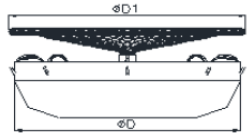


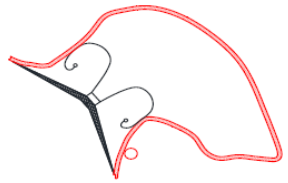
Safely stabilized anchoring mechanism

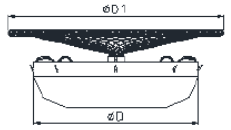
- 8 small hooks (engage into LAA walls)
- 8 individual U-shaped ends (trapped in trabeculations)
- Over-sized umbrella (pushing and stenting against the LAA)



Device Sizes and Corresponding Delivery Systems of LAmbre







Cat.	Diameter of Umbrella(mm)	Diameter of Cover(mm)	Delivery system
LT-LAA-1622	16	22	8F-900 9F-900 10F-900
LT-LAA-1824	18	24	
LT-LAA-2026	20	26	9F-900 10F-900
LT-LAA-2228	22	28	
LT-LAA-2430	24	30	
LT-LAA-2632	26	32	10F-900
LT-LAA-2834	28	34	
LT-LAA-3036	30	36	
LT-LAA-3236	32	36	
LT-LAA-3438	34	38	
LT-LAA-3640	36	40	

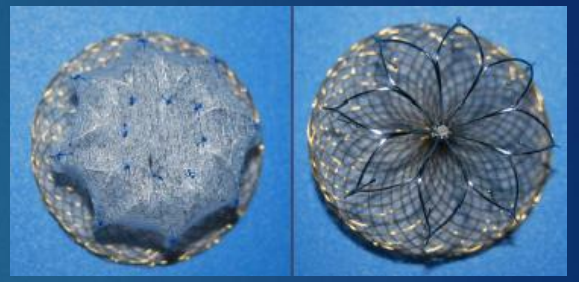
Cat.	Diameter of Umbrella(mm)	Diameter of Cover(mm)	Delivery system
LT-LAA-1630	16	30	9F-900 10F-900
LT-LAA-1832	18	32	10F-900
LT-LAA-2032	20	32	
LT-LAA-2234	22	34	
LT-LAA-2436	24	36	
LT-LAA-2638	26	38	

LAA landing zone/ostium/depth measurement and Size Selection

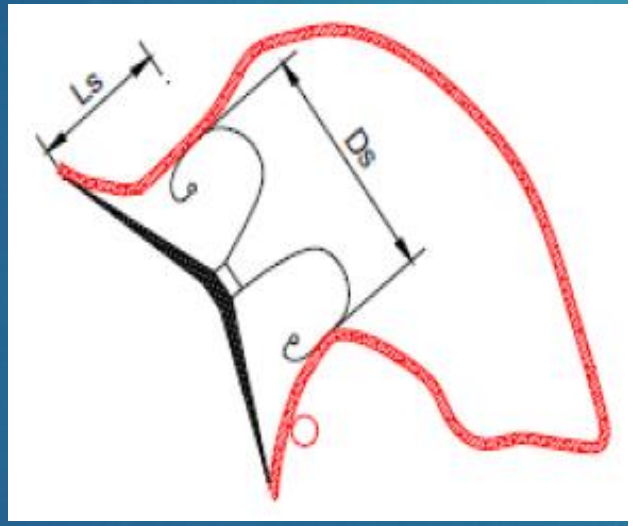
- Choose an Occluder 3-8mm larger than the measured landing zone;
- Selection of a Special-type Occluder (small umbrella with a relatively big cover) may be considered if the ostium is 10mm than landing zone)

Special LAA Morphology

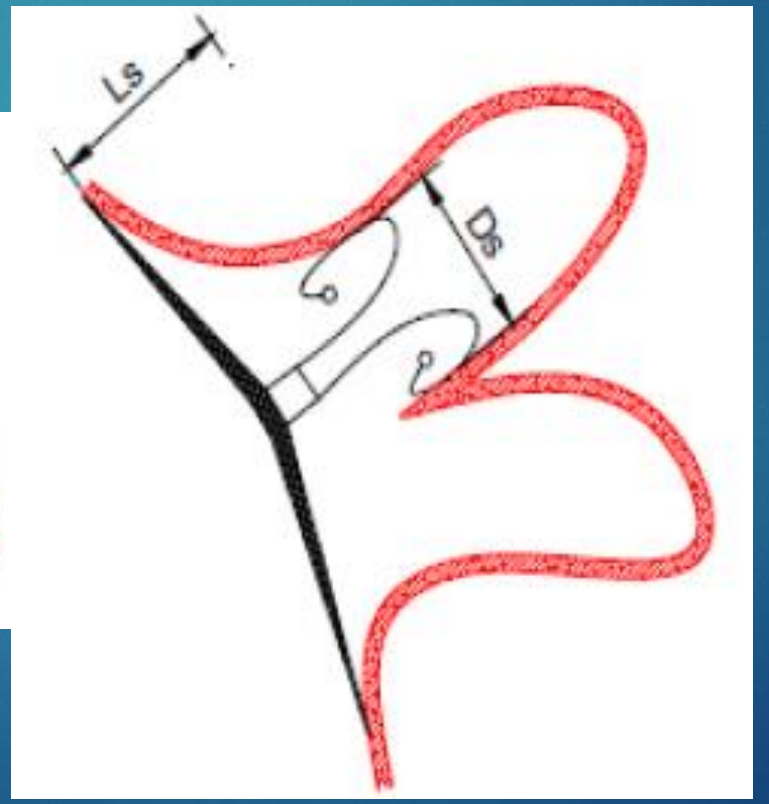
- Small LAA
- LAA with multiple lobes and restrictive septum



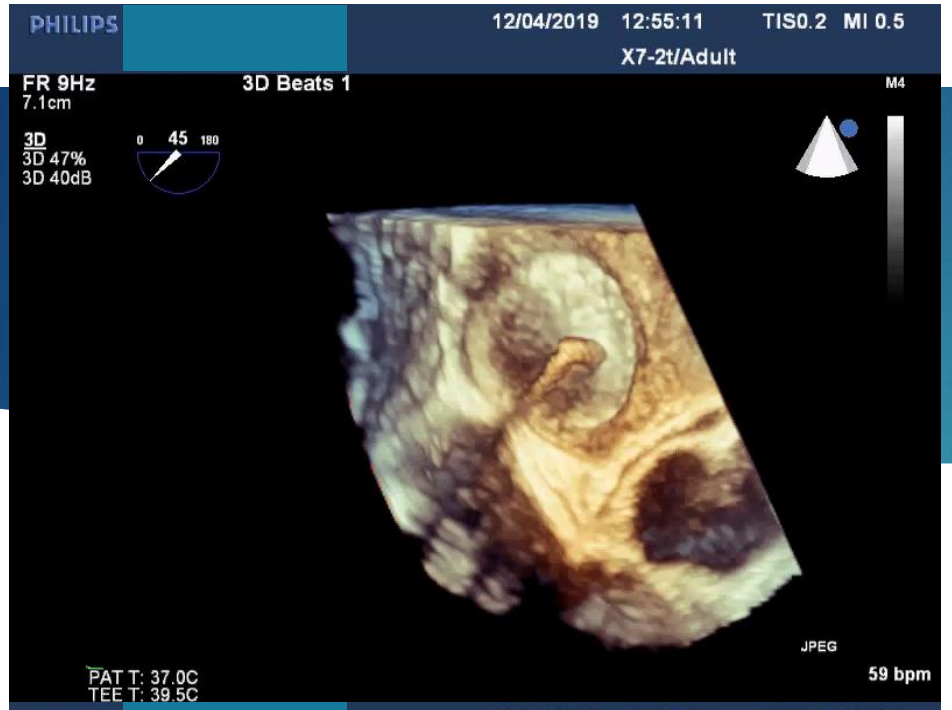
Size: 16-26mm
Cover 12mm larger



Size: 16-36mm
Cover 4-6mm larger



HKU Med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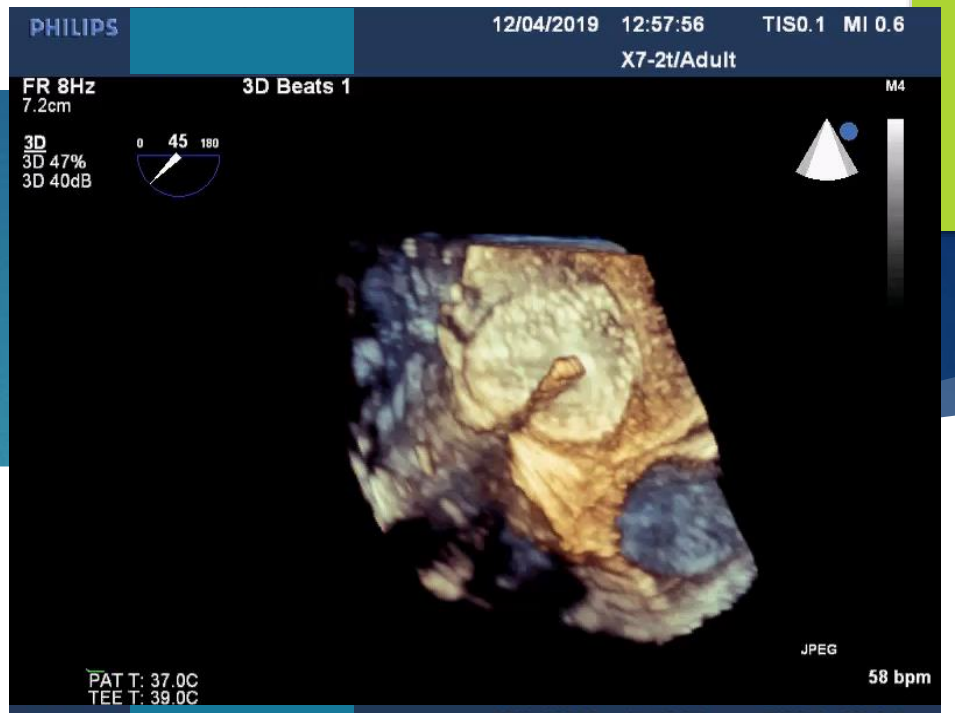
12/04/2019 12:55:11 TIS0.2 MI 0.5
X7-2t/Adult
FR 9Hz
7.1cm
3D Beats 1
M4
3D
3D 47%
3D 40dB
0 45 180
JPEG
PAT T: 37.0C
TEE T: 39.5C
59 bpm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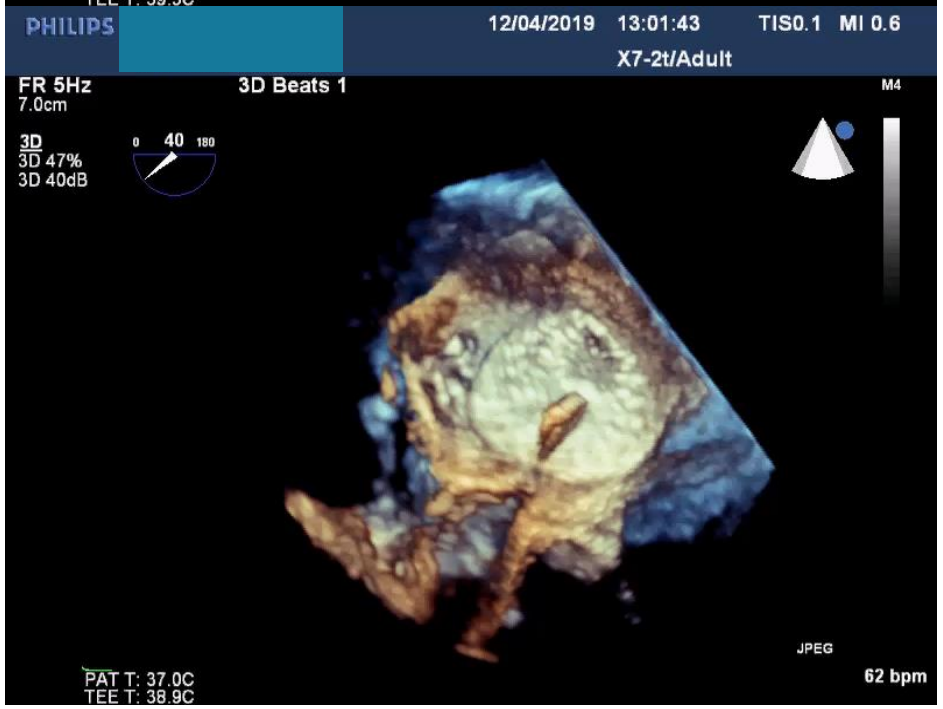
12/04/2019 12:57:56 TIS0.1 MI 0.6
X7-2t/Adult
FR 8Hz
7.2cm
3D Beats 1
M4
3D
3D 47%
3D 40dB
0 45 180
JPEG
PAT T: 37.0C
TEE T: 39.0C
58 bpm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FR 5Hz
7.0cm
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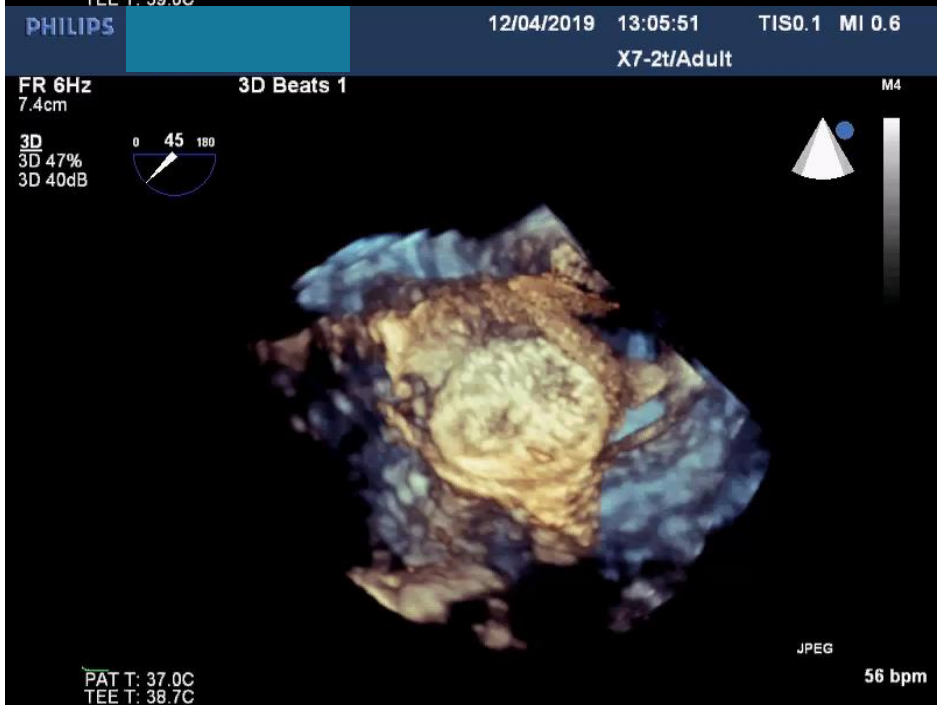
M4
3D
3D 47%
3D 40dB
0 40 180
JPEG
PAT T: 37.0C
TEE T: 38.9C
62 bpm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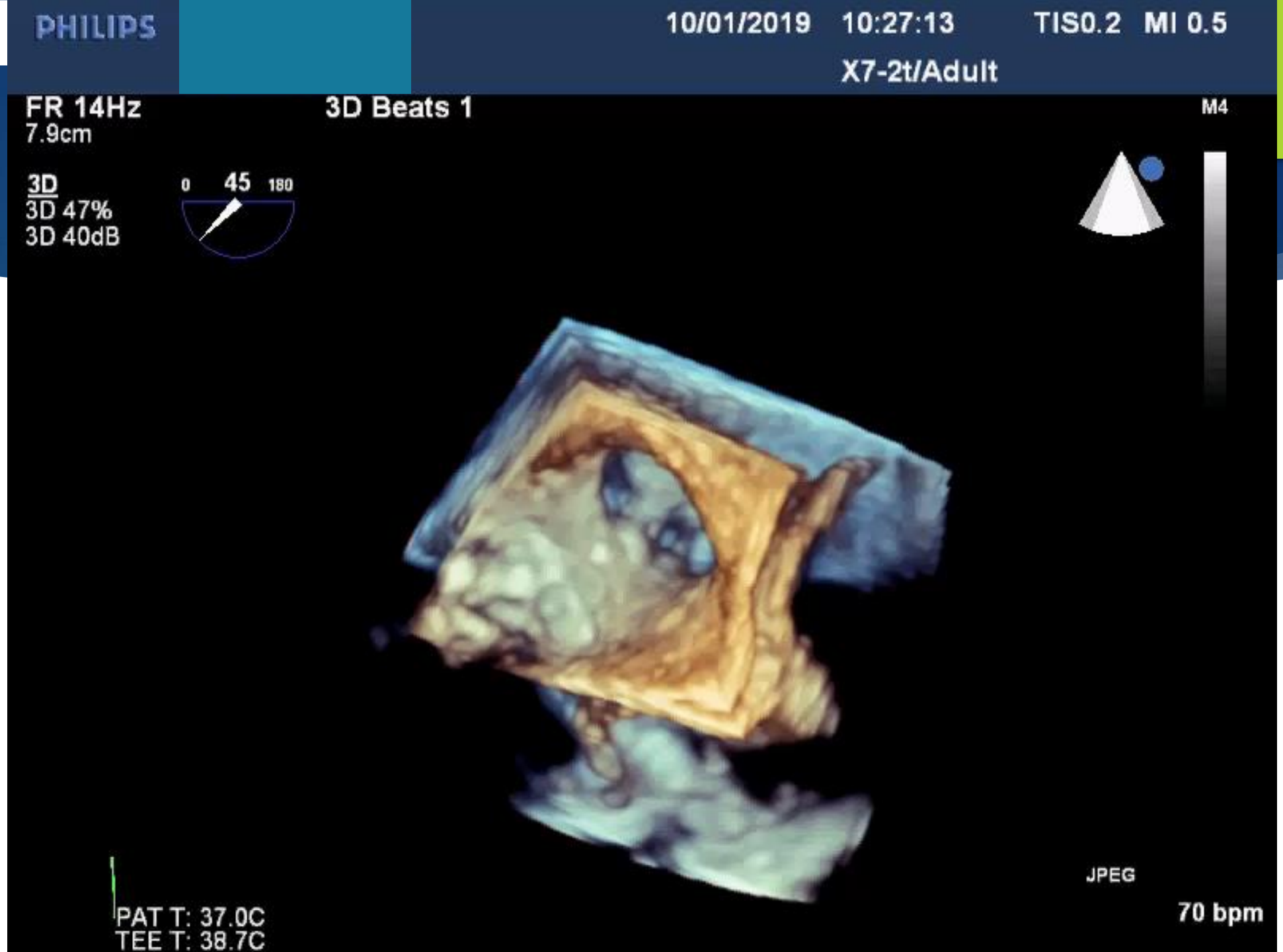
12/04/2019 13:05:51 TIS0.1 MI 0.6
X7-2t/Adult
FR 6Hz
7.4cm
3D Beats 1
M4
3D
3D 47%
3D 40dB
0 45 180
JPEG
PAT T: 37.0C
TEE T: 38.7C
56 bpm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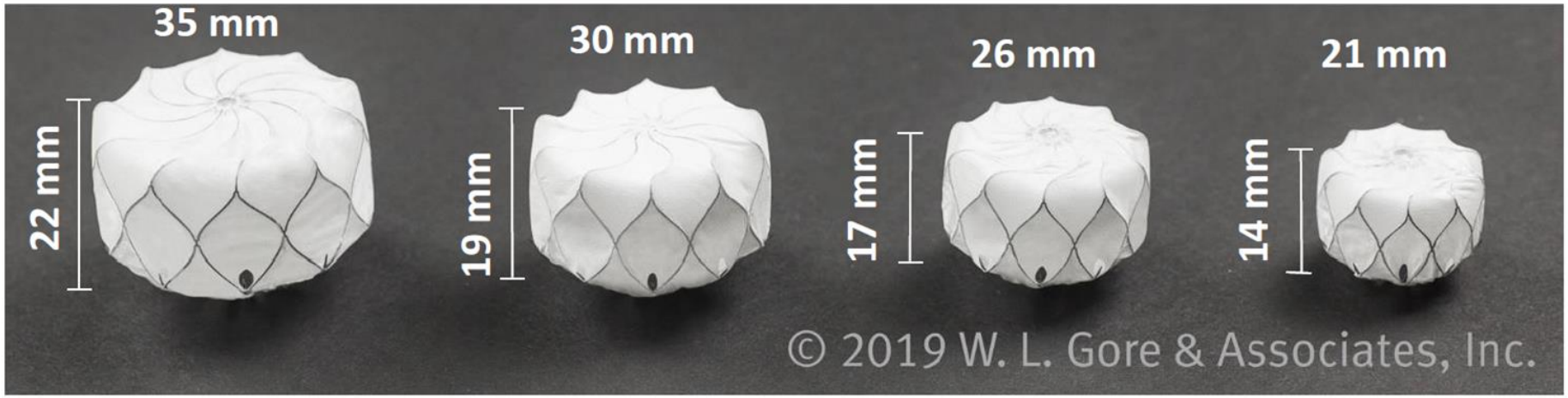
10/01/2019 10:27:13 TIS0.2 MI 0.5
X7-2t/Adult
FR 14Hz
7.9cm
3D Beats 1
M4
3D
3D 47%
3D 40dB
0 45 180
JPEG
70 bpm
PAT T: 37.0C
TEE T: 38.7C

New LAAO Devices

GORE CARDIOFROM LAA Occluder

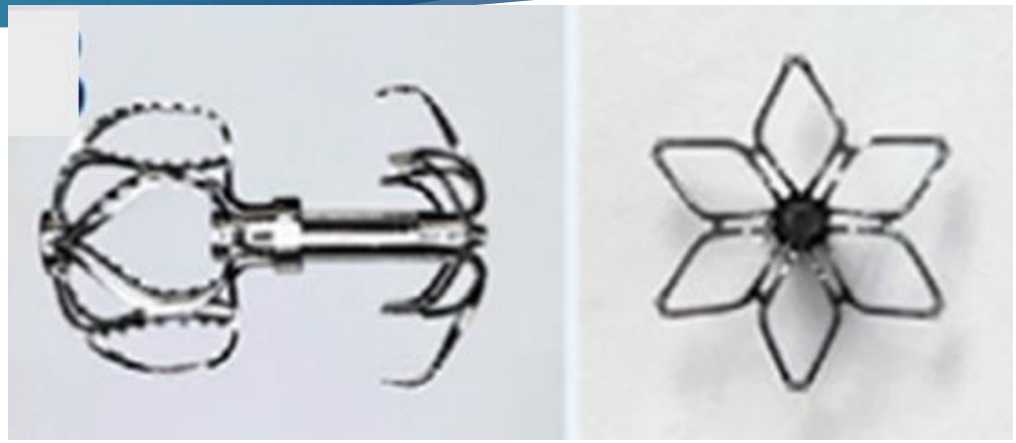
- Soft, conformable, with flat atrial surface
- Open distal end for minimal elongation when compressed
- Retractable anchors allow for full retrieval with low forces

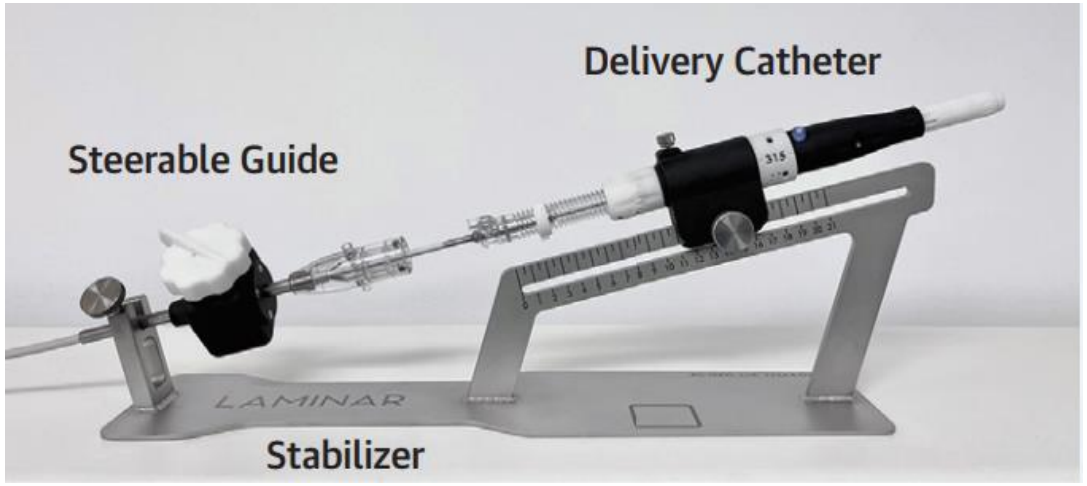
CBAS® Heparin Surface
- The CBAS® Heparin Surface is utilized to bind heparin molecules to the ePTFE via a proprietary covalent end-point attachment mechanism



LAMINAR – LAA Exclusion

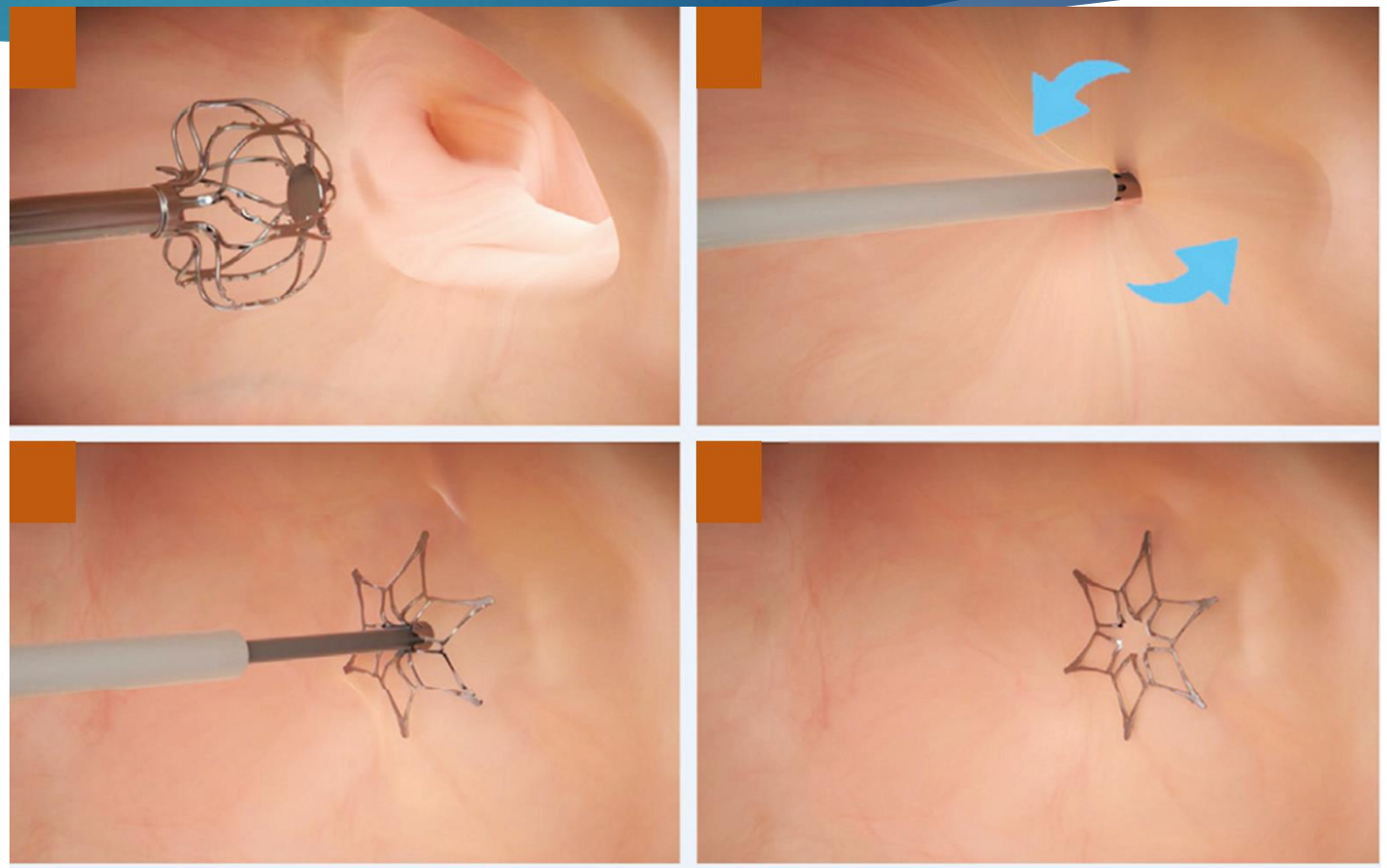
- 2 integrated components – **BALL** and **LOCK**
- Self-expandable **nitinol sphere** without side hooks/barbs
- Lock – flower-shaped 6 petals, interlock with the ball to achieve tissue compression and seal
- 2 Sizes for the Ball – 12mm and 16mm
- 18Fr steerable guide and delivery catheter

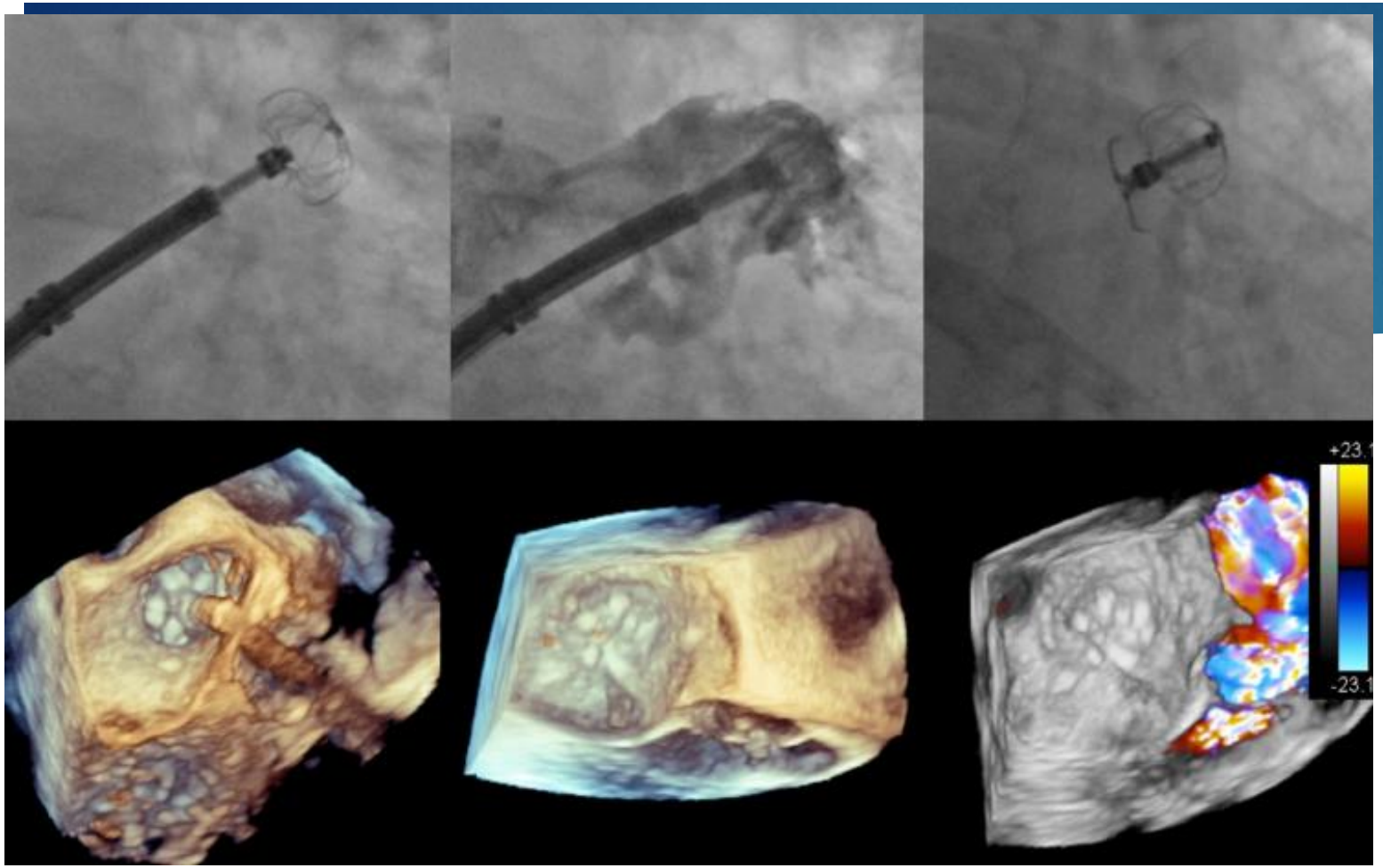


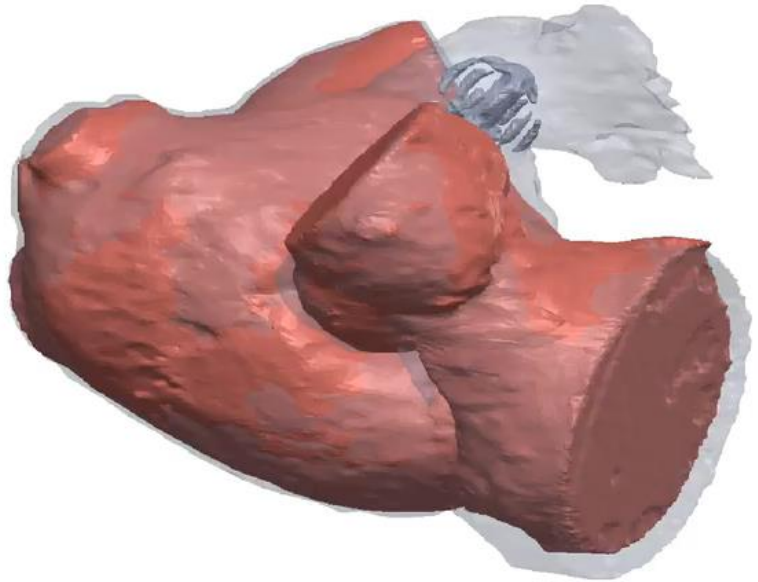


LAMINAR – LAA Exclusion

- **"Rotational closure"**
- Ball directed to LAA upon in touch with backwall
- Rotate counter-clockwise to engage LAA tissue approx. 360 degree
- LAA tissue being brought together circumferentially and wraps about the spindle (connection)
- Locked by 6-pedals design





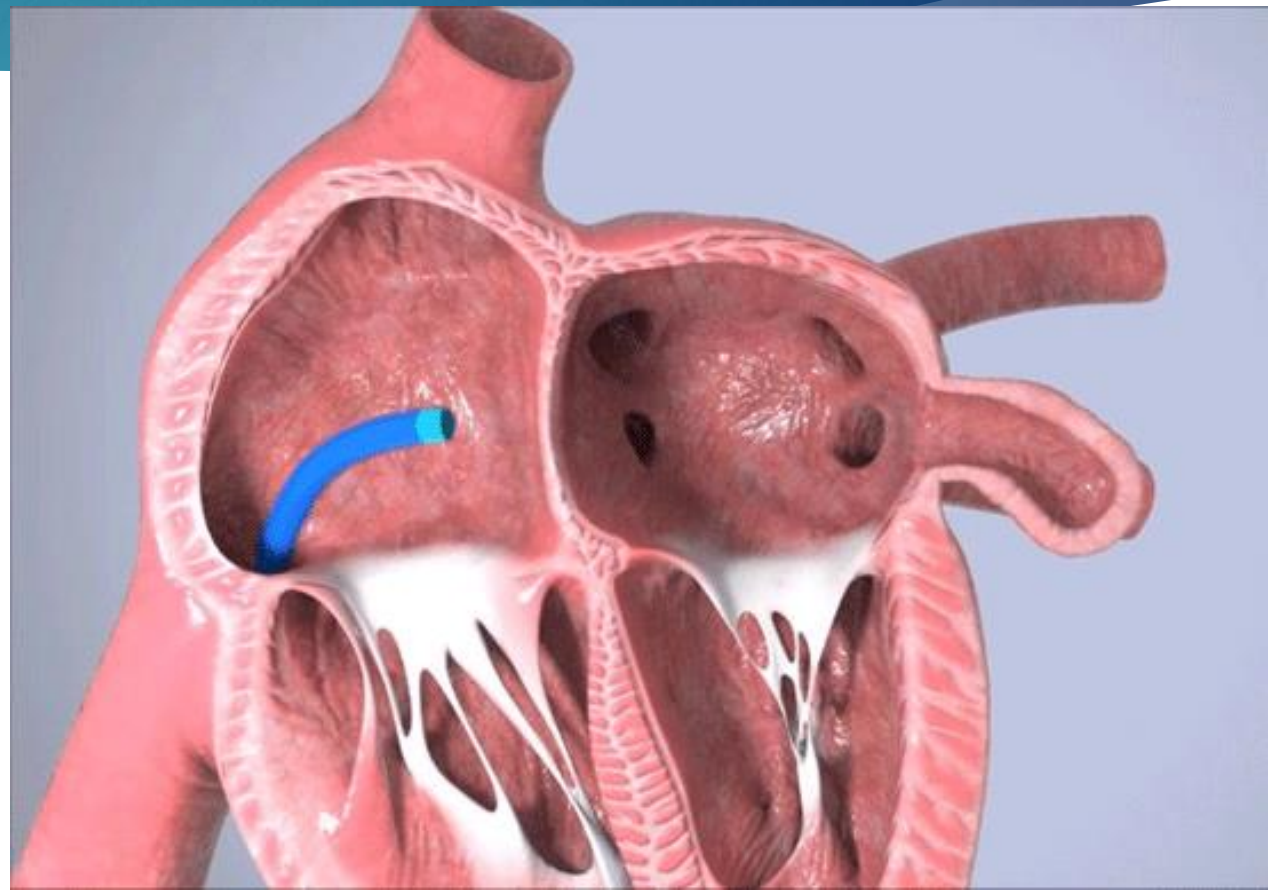


- FIH – **N = 15**
- 100% implant success
- No periprocedural/post procedural safety events
- No DRT/Leak at 7 days, 45 days, 6 months and 12 months

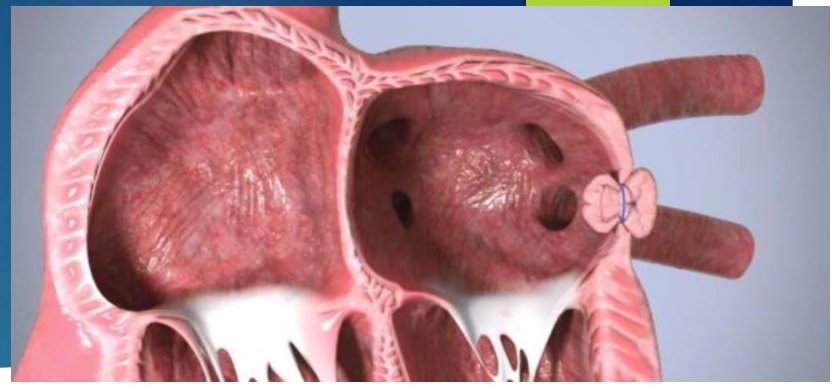
Wong GX, Kar S, Smith TW, Spangler T, Bolling SF, Rogers JH. Transcatheter Left Atrial Appendage Exclusion: Preclinical and Early Clinical Results With the Laminar Device. JACC Cardiovasc Interv. 2023 Jun 12;16(11):1347-1357

APPLIGATOR – Append Medical

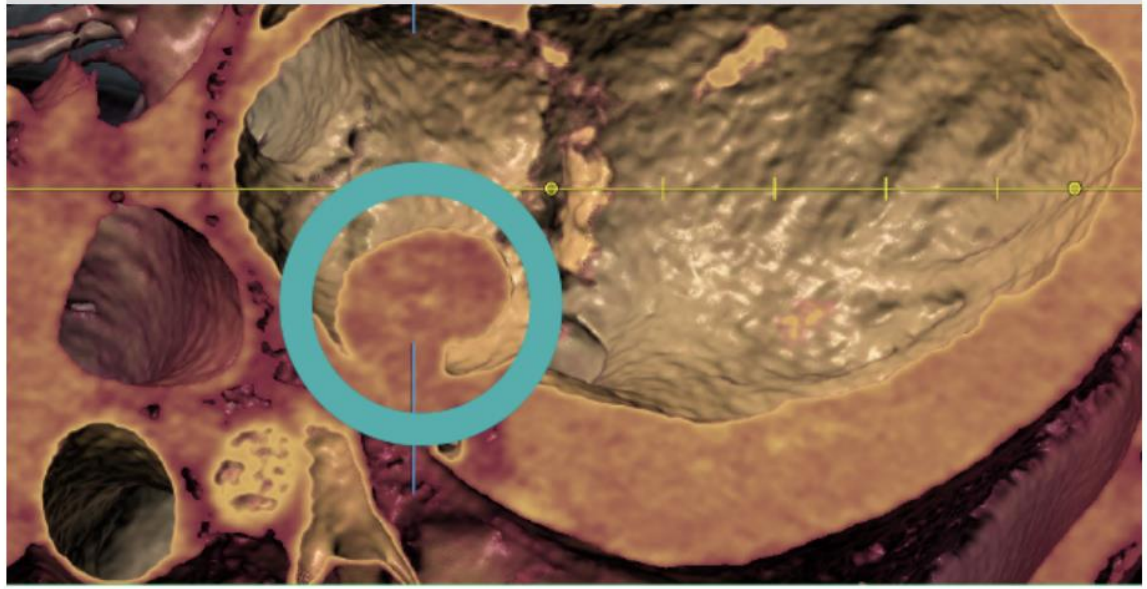
- **Non-device based closure**
- Capture LAA from inside
- Tissue Manipulation
- Suture – Invagination LAA into left atrium



Appligator – Append Medical

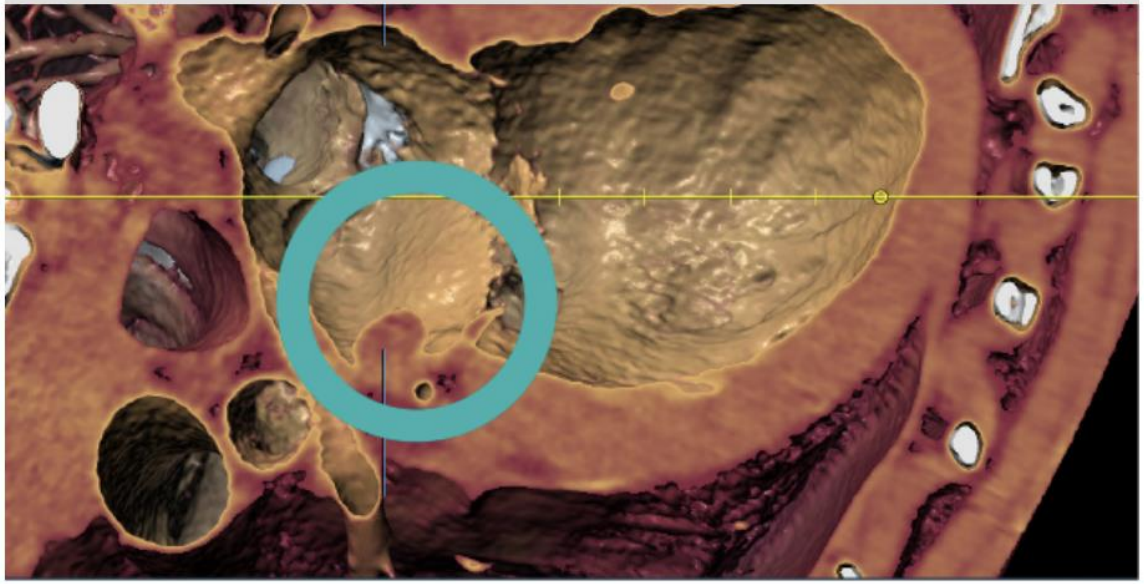


CT SCAN 3 DAYS POST IN-VIVO CHRONIC PROCEDURE



INVAGINATED SEALED LAA

CT SCAN 146 DAYS POST IN-VIVO CHRONIC PROCEDURE



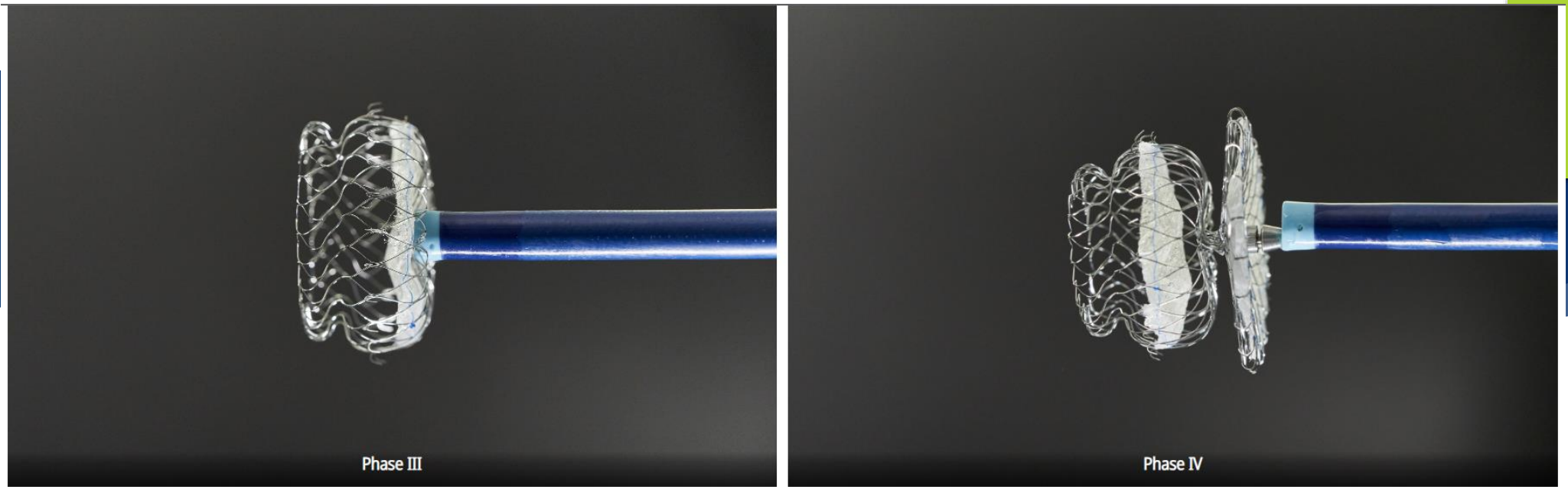
95% VOLUME DECREASE

CORMOS LAA Occluder

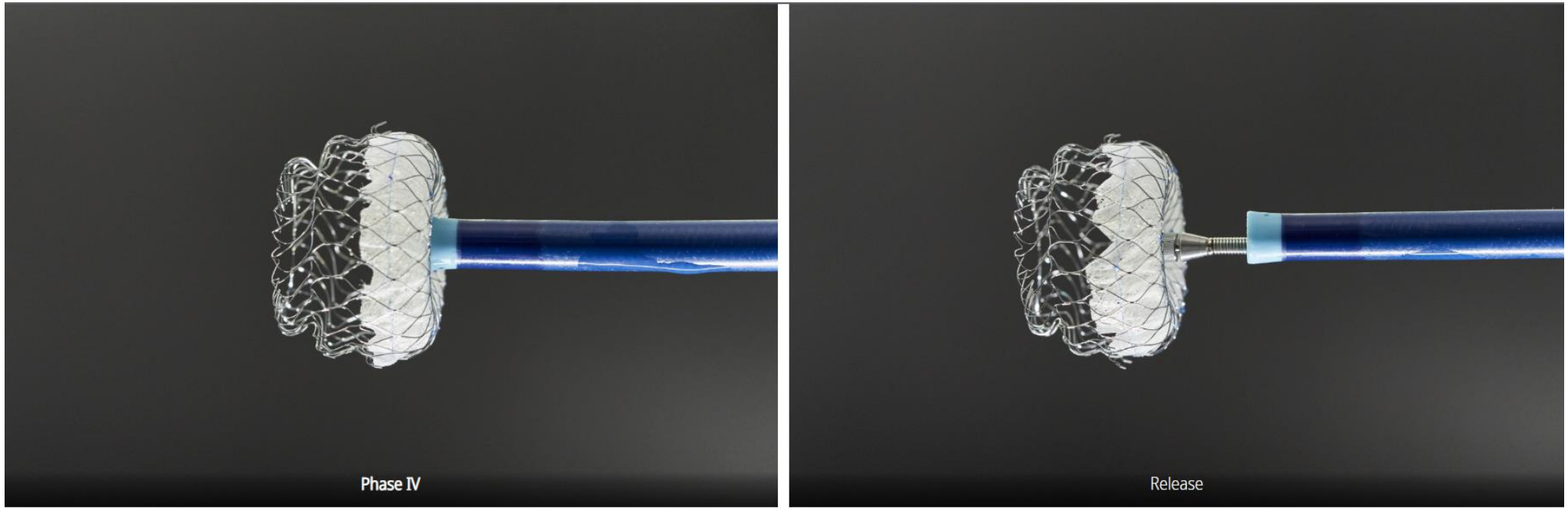
- Type I with disc
- Cormos-LAA-Occluder *MATRIX*

- Type II without disc
- Cormos-LAA-Occluder *RUBIN*

In vivo study: Animal model (Started in March 2019)
FIM 6/2020



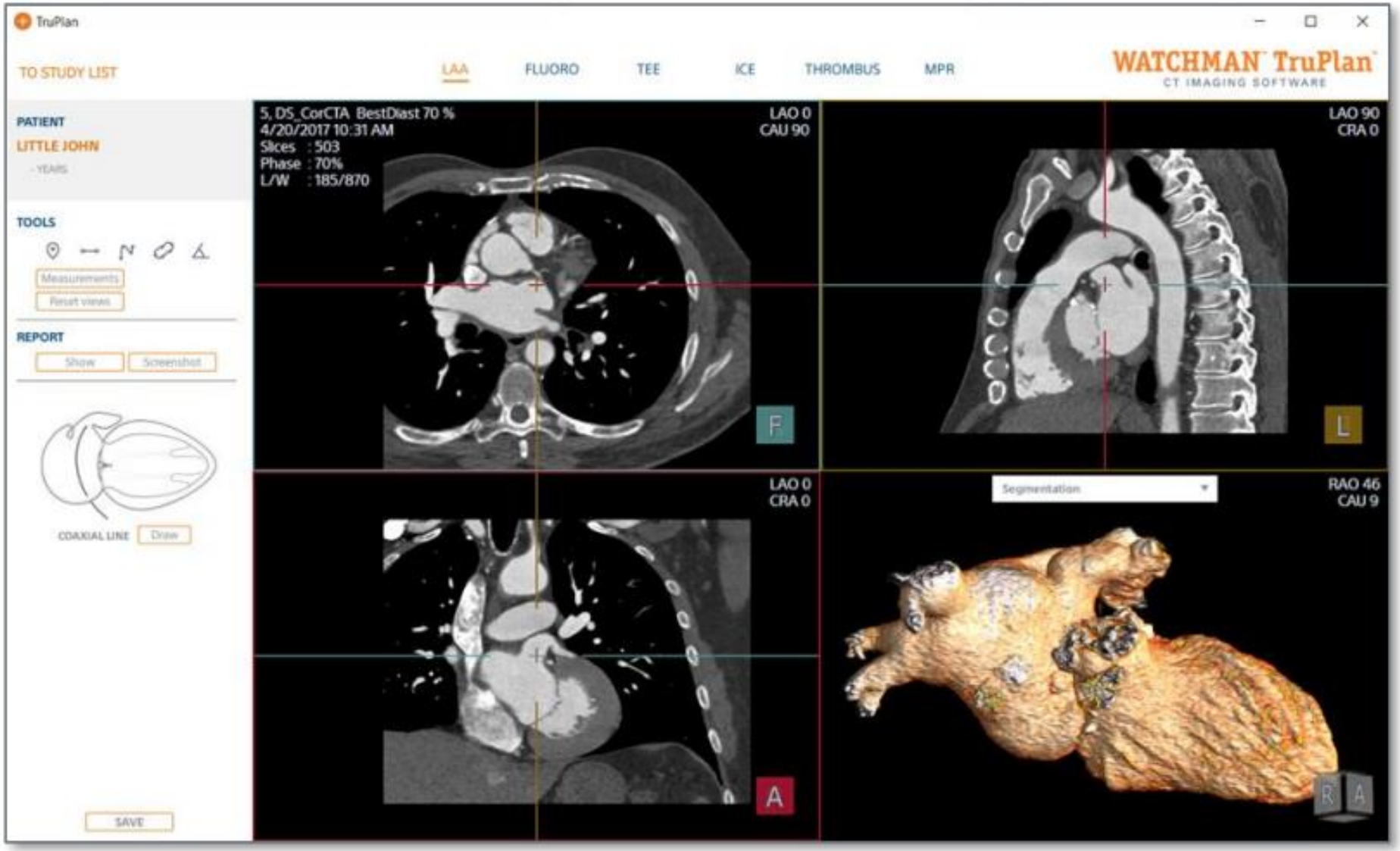
Cormos® Medical LAA-Occluder Typ I with exit in 4 phases



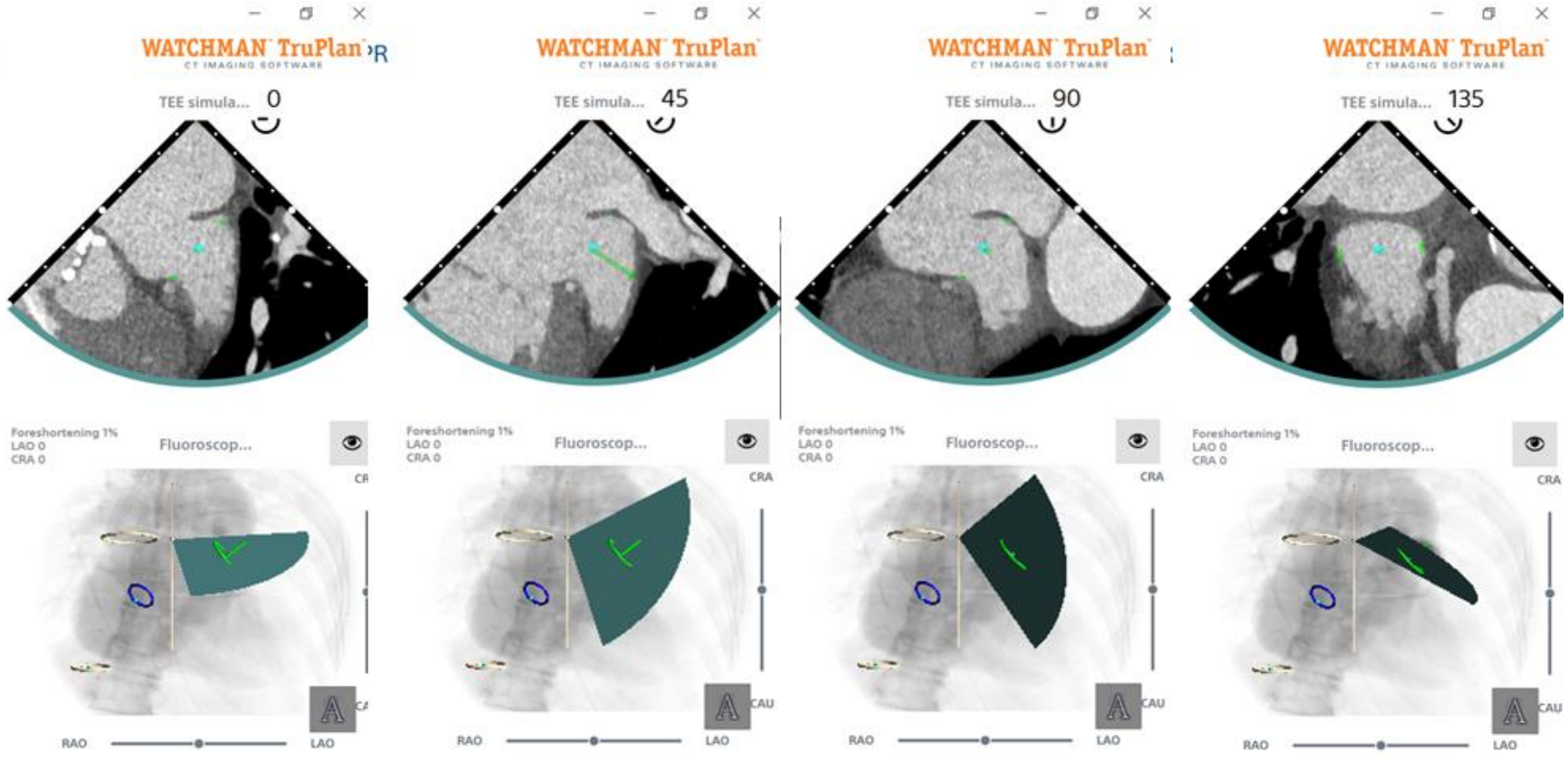
Cormos® Medical LAA-Occluder Typ II with exit in 4 phases

New in Pre-procedural Planning

CT Analysis Workflow – WATCHMAN TruPlan



Fluoro – TEE Simulation



WATCHMAN FLX Implant Simulation

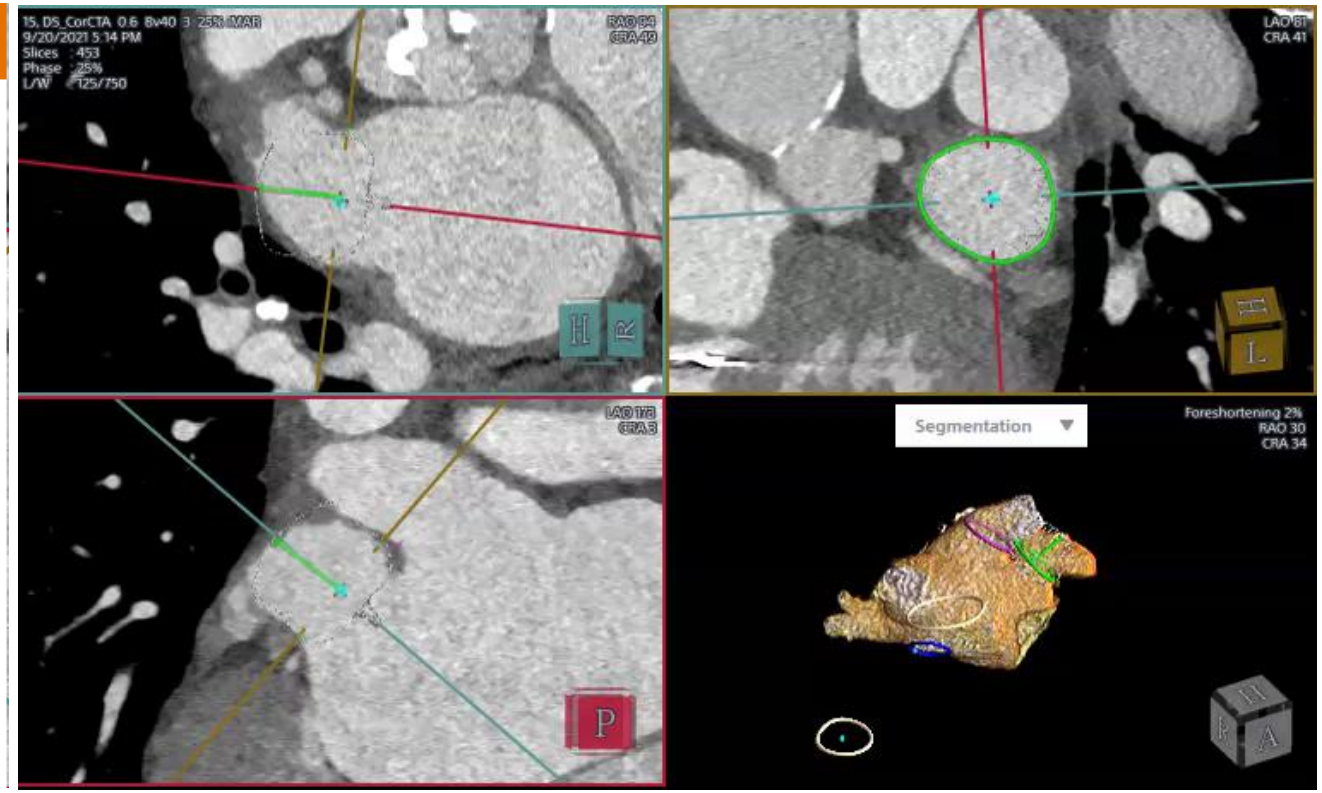
SIZING TABLES

Measured: Max Ø 31.2mm

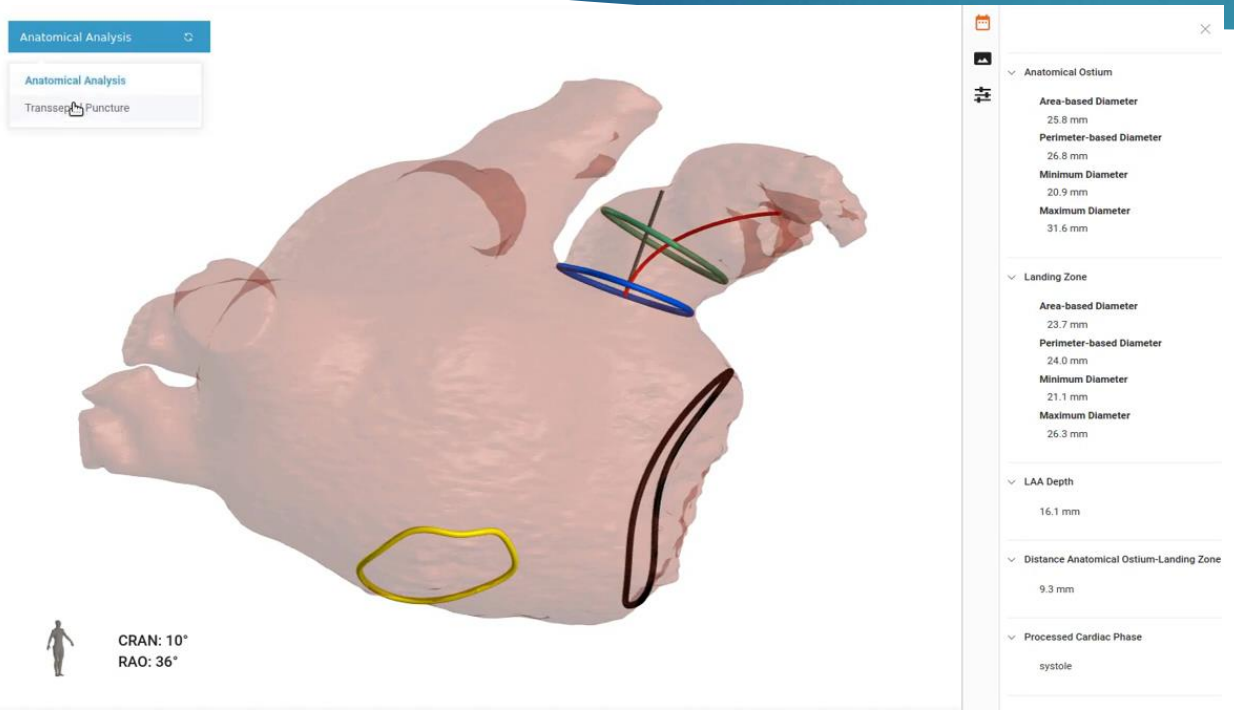
Shown: WATCHMAN FLX 35mm 15%

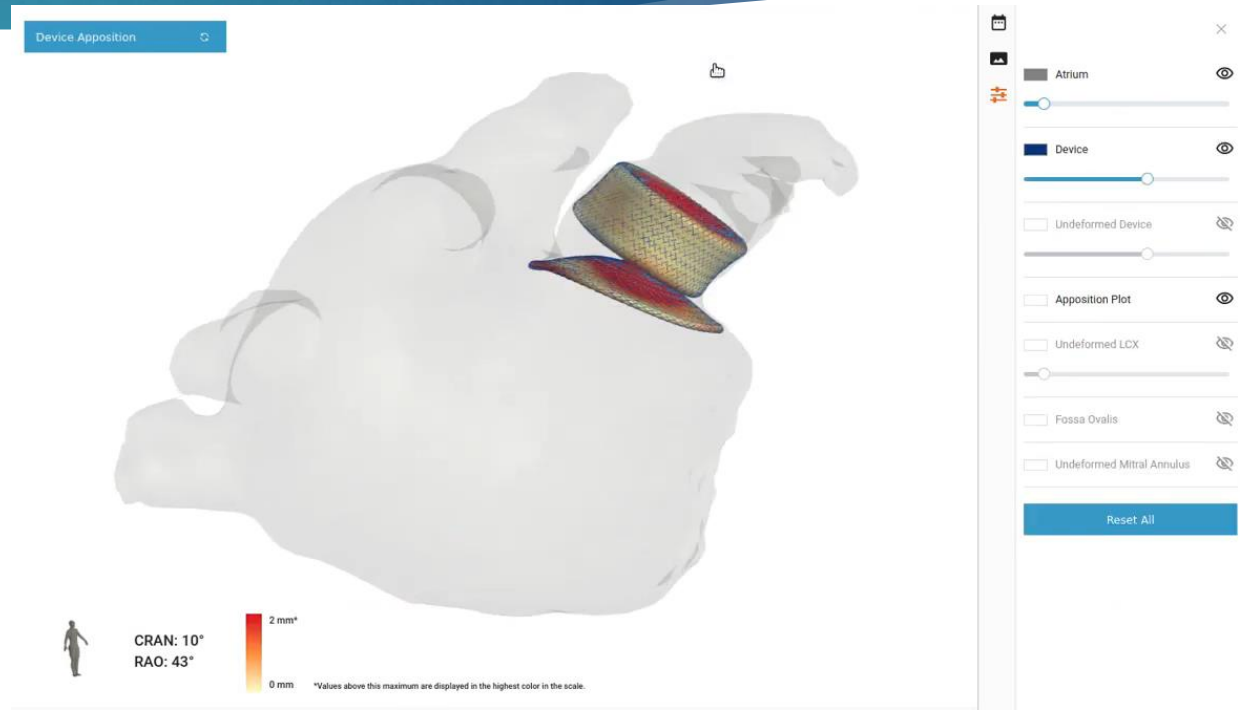
WATCHMAN FLX

Max diameters	Device size	Est. compression	Show
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	11 %	☑



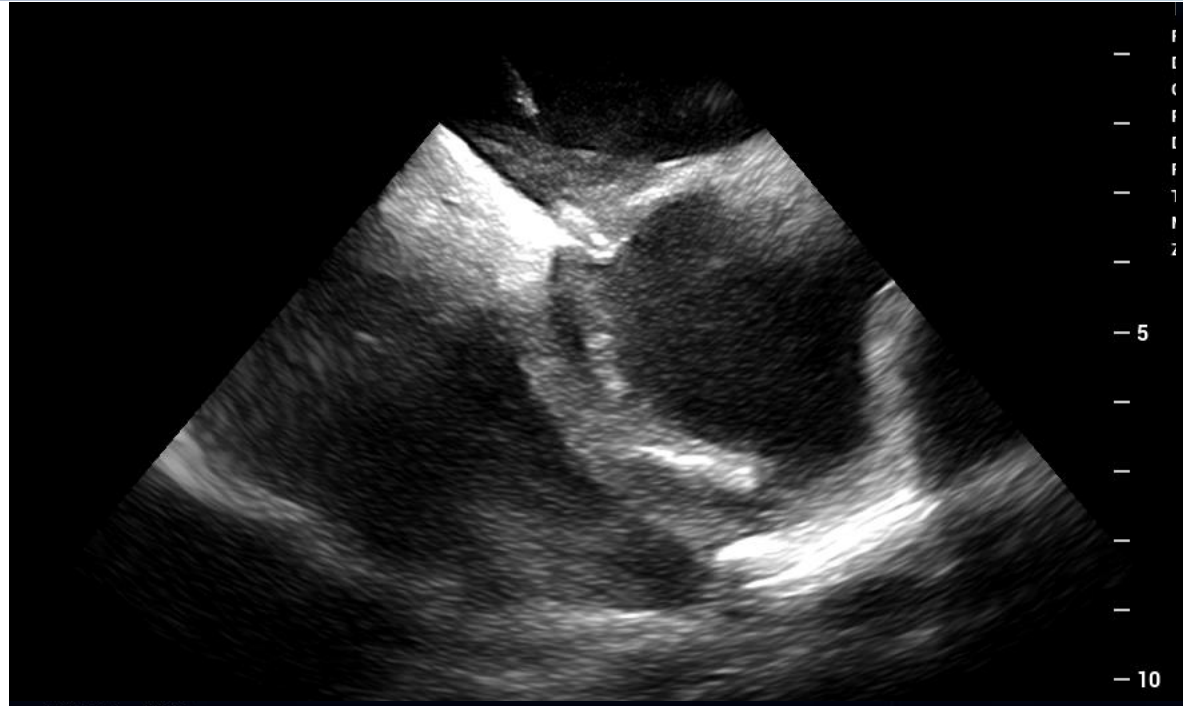
CT Analysis Workflow - FEOPS

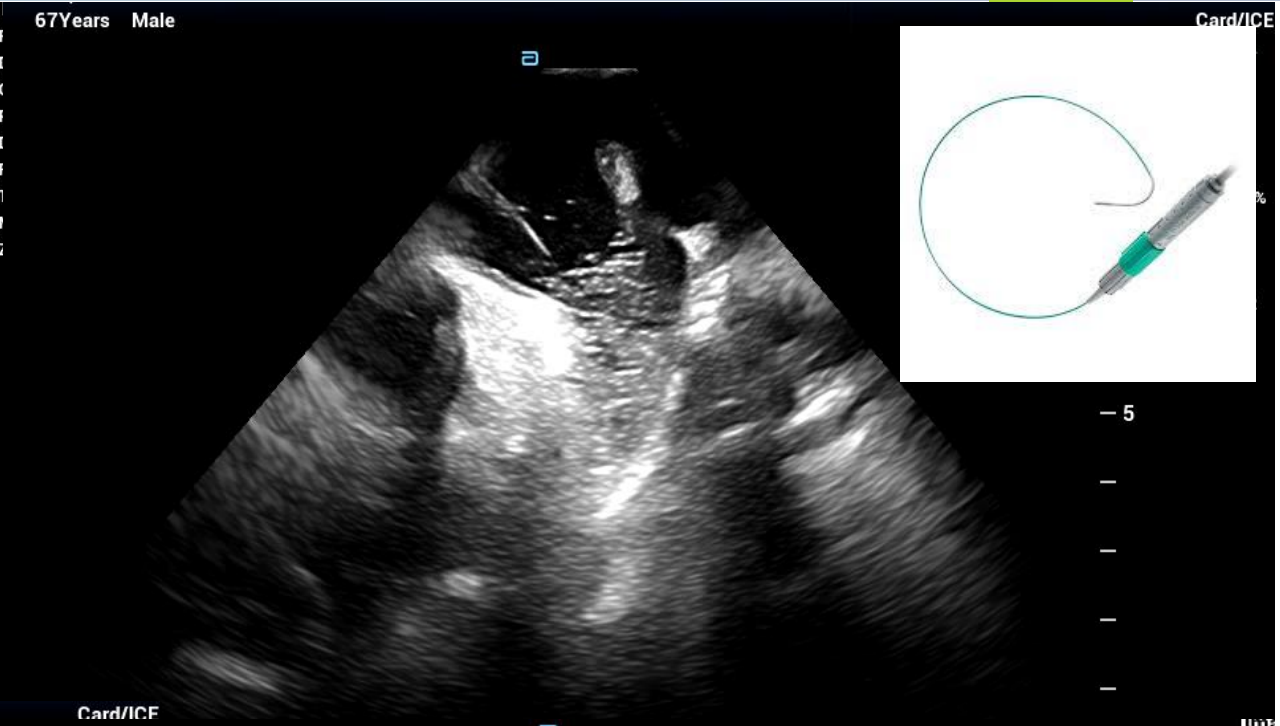


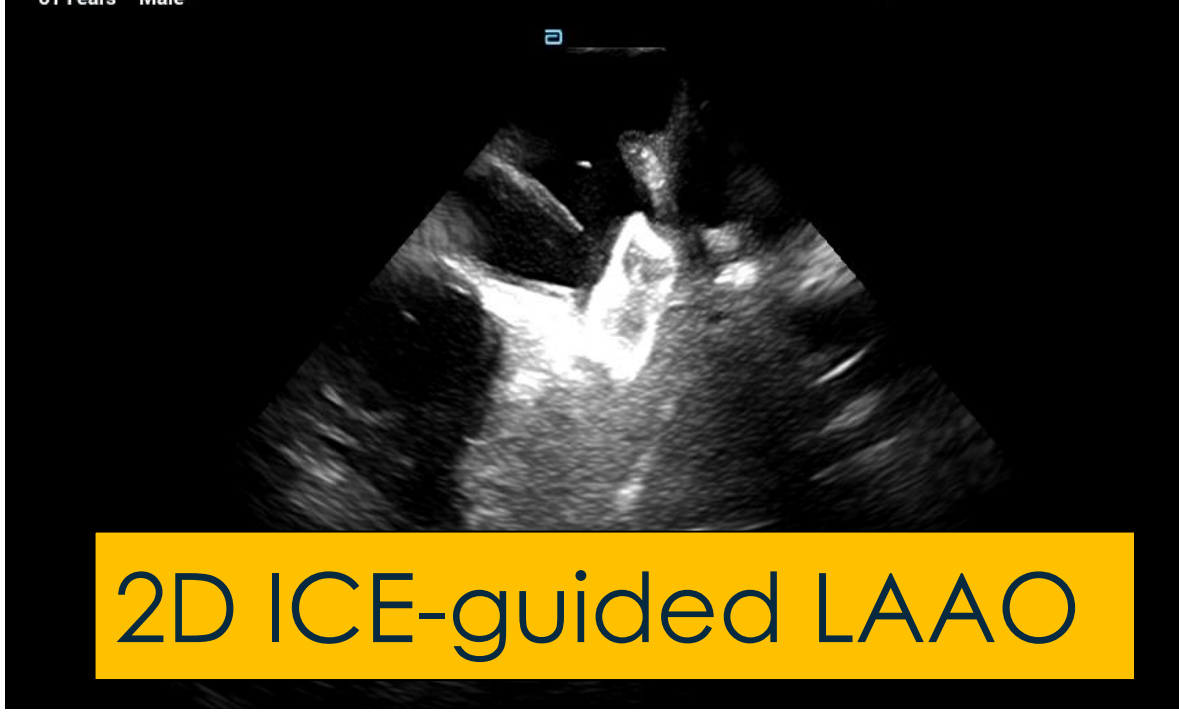


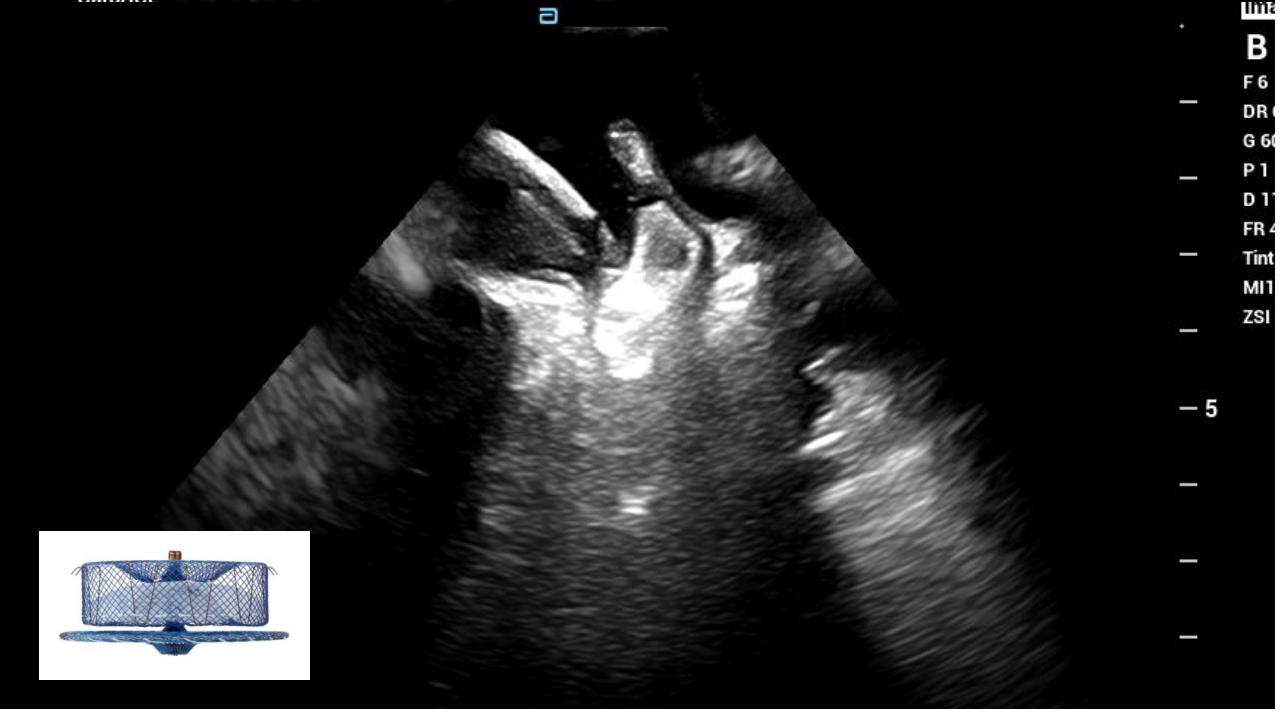
https://feops.com/product/healthcare-professionals#laao-tab

New in Procedural Workflows





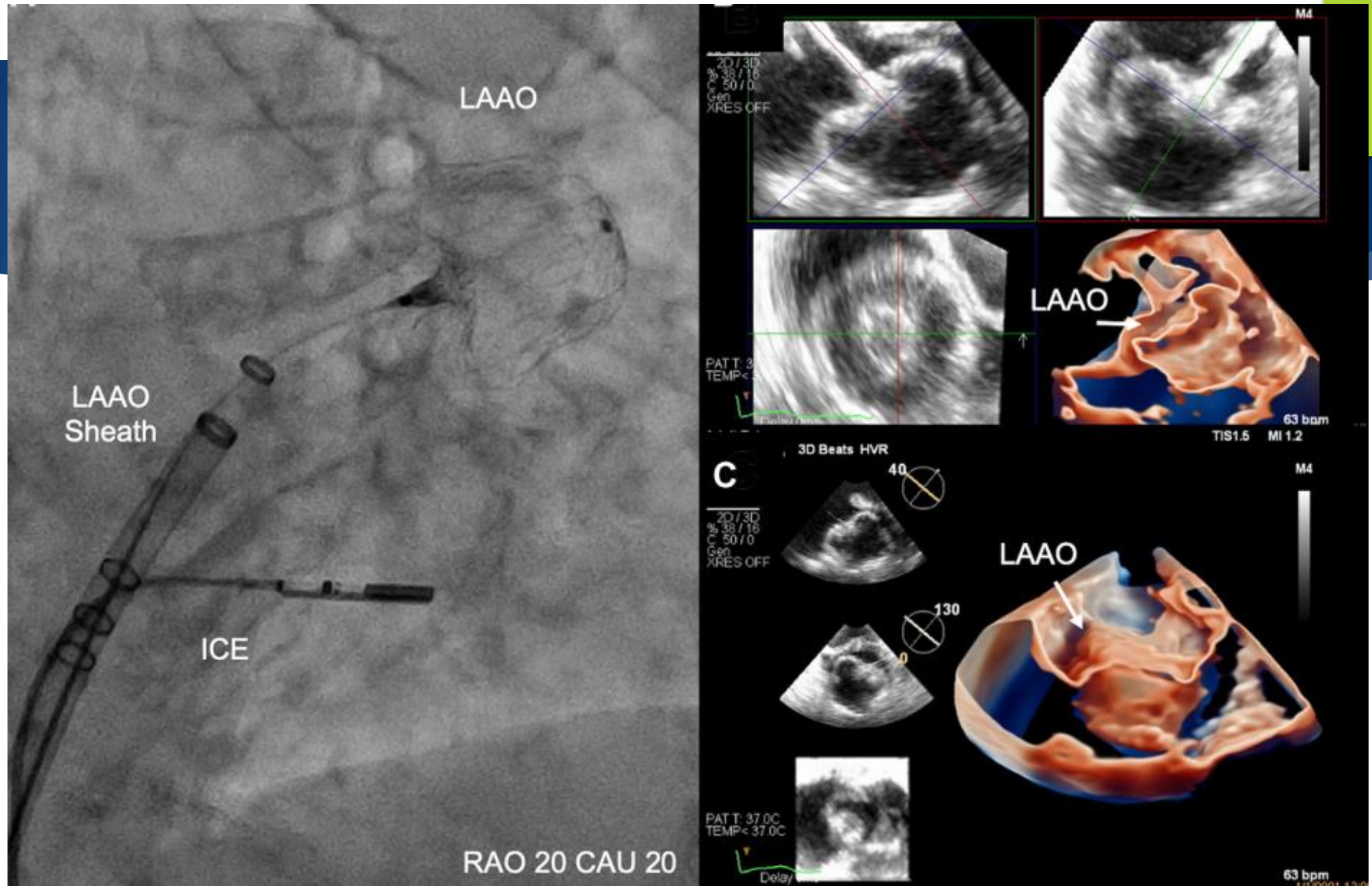




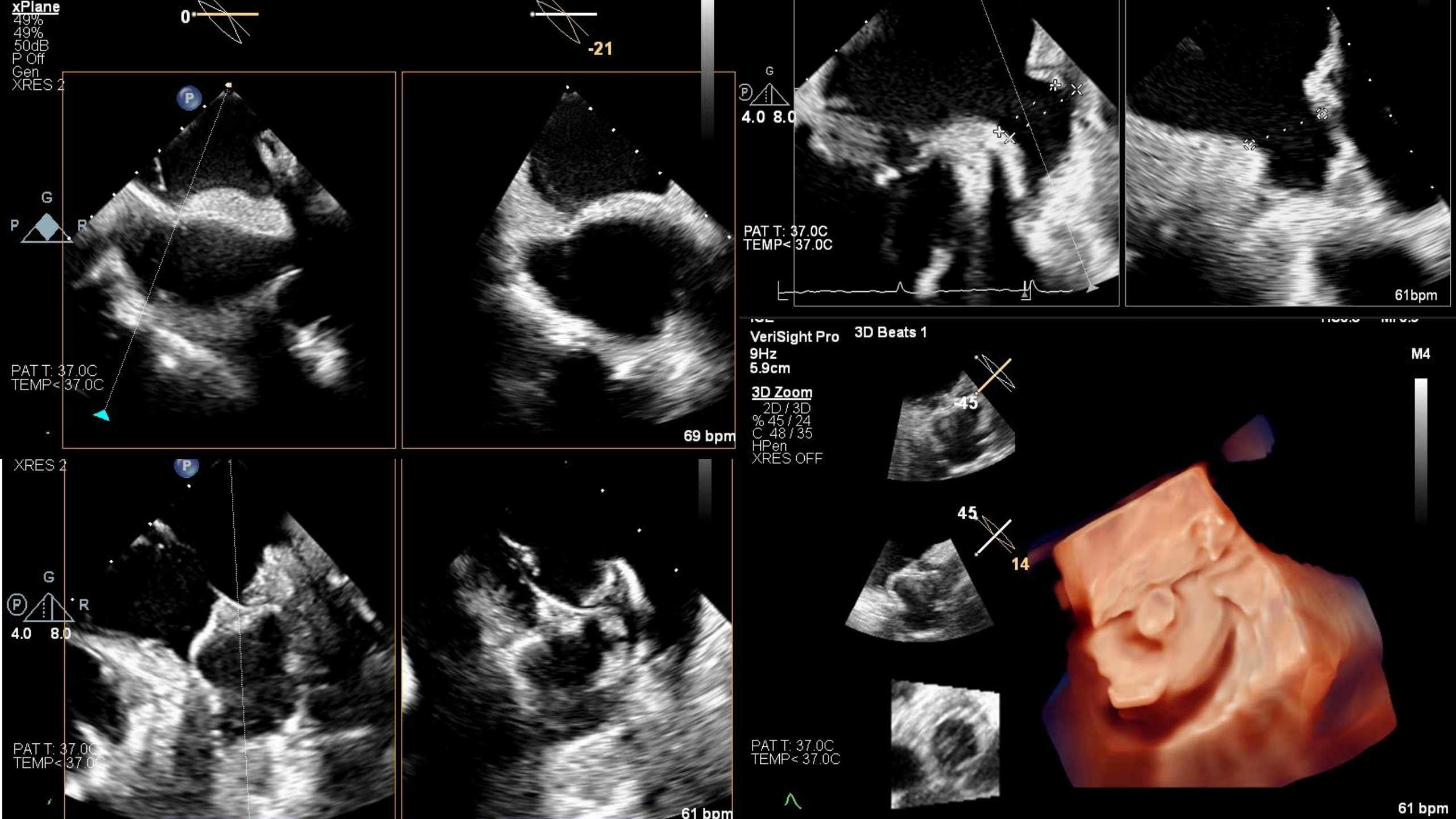
2D ICE-guided LAAO

LAA under 3D ICE

- PHILIPS VeriSight-Pro
- SIEMENS ACUSON AcuNAV Volume 4D ICE Catheter



Alkhouli M, Simard T, Killu AM, Friedman PA, Padang R. First-in-Human Use of a Novel Live 3D Intracardiac Echo Probe to Guide Left Atrial Appendage Closure. JACC Cardiovasc Interv. 2021 Nov 8;14(21):2407-2409. doi: 10.1016/j.jcin.2021.07.024. Epub 2021 Aug 25. PMID: 34454857.


xPlane
49%
49%
50dB
P Off
Gen
XRES 2
0
-21
G
P
R
PAT T: 37.0C
TEMP< 37.0C
69 bpm
4.0 8.0
61bpm
VeriSight Pro
9Hz
5.9cm
3D Zoom
2D / 3D
% 45 / 24
C 48 / 35
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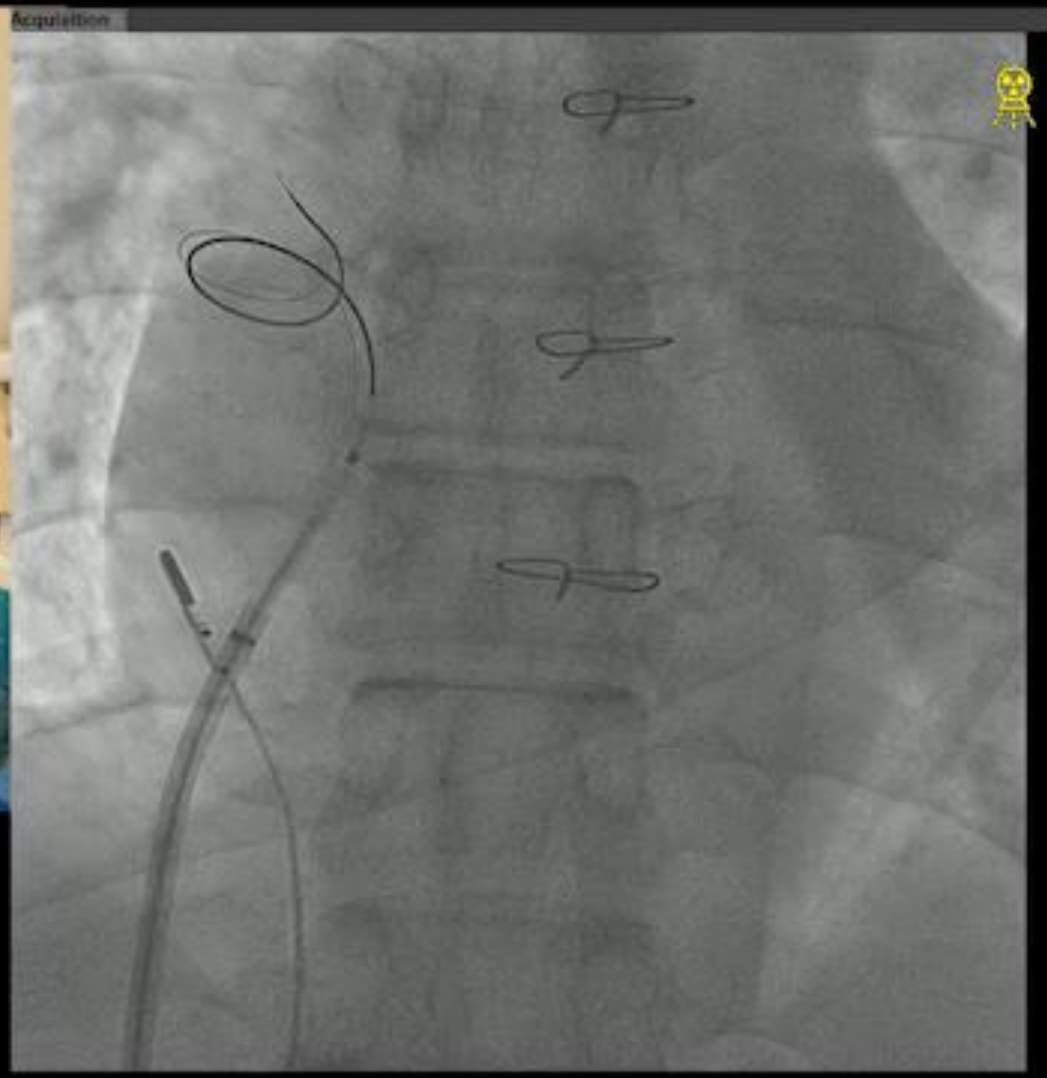
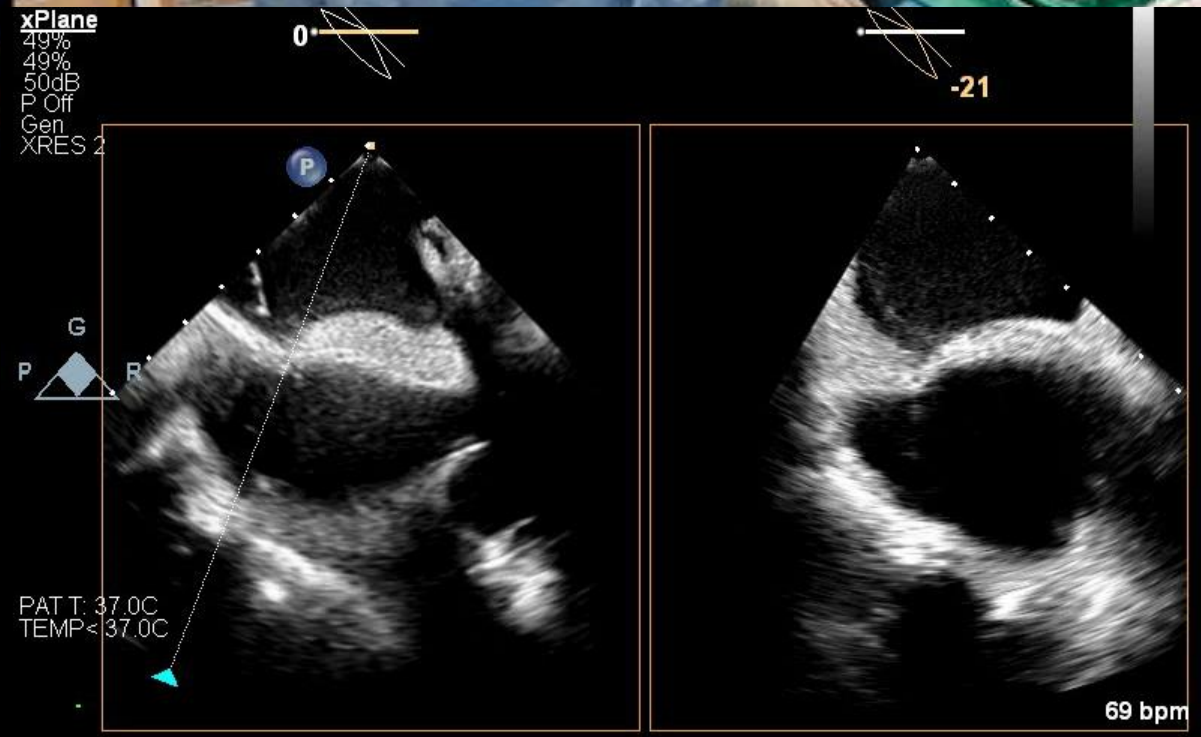
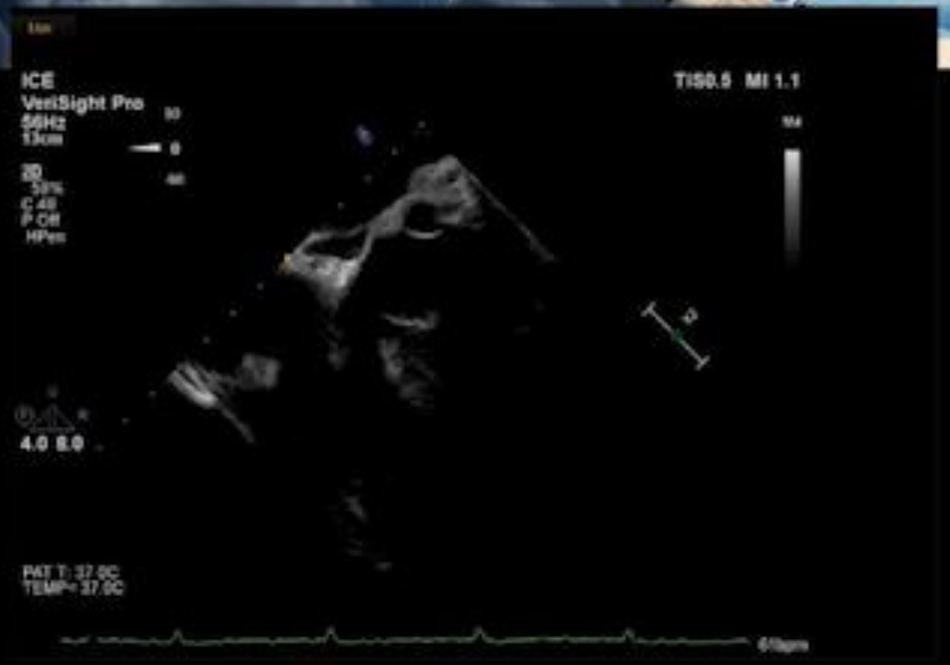
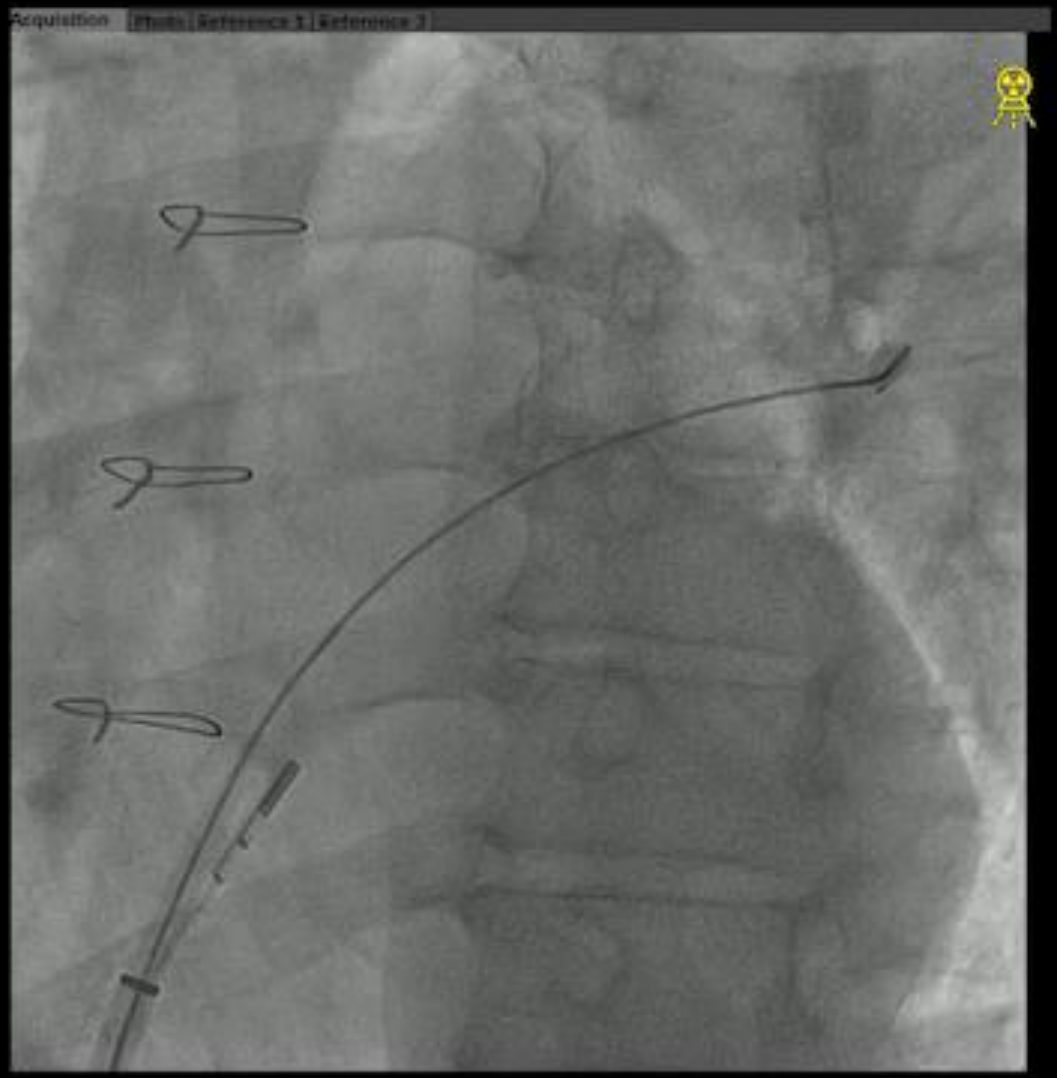
3D Beats 1
M4
-45
45
14
61 bpm





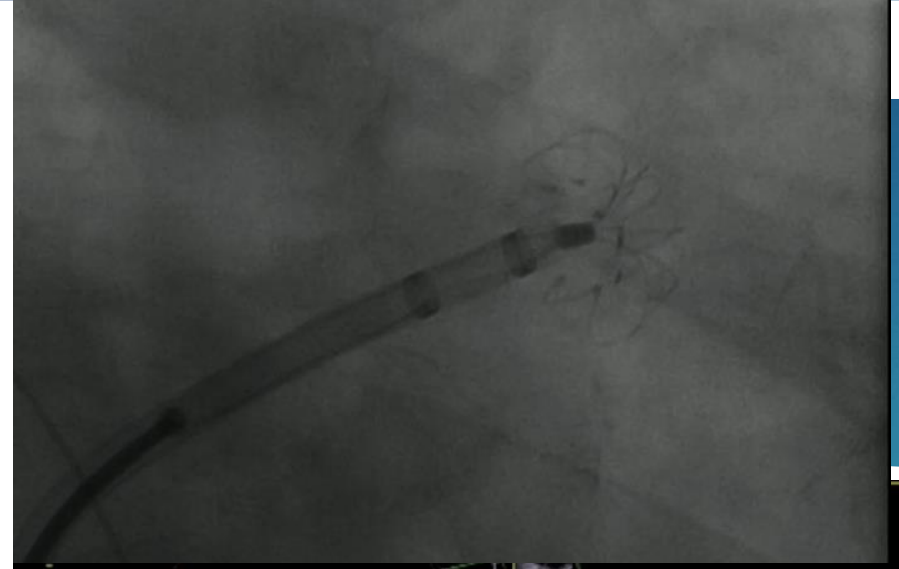
HONG KONG VALVES
HEART TEAM CONFERENCE



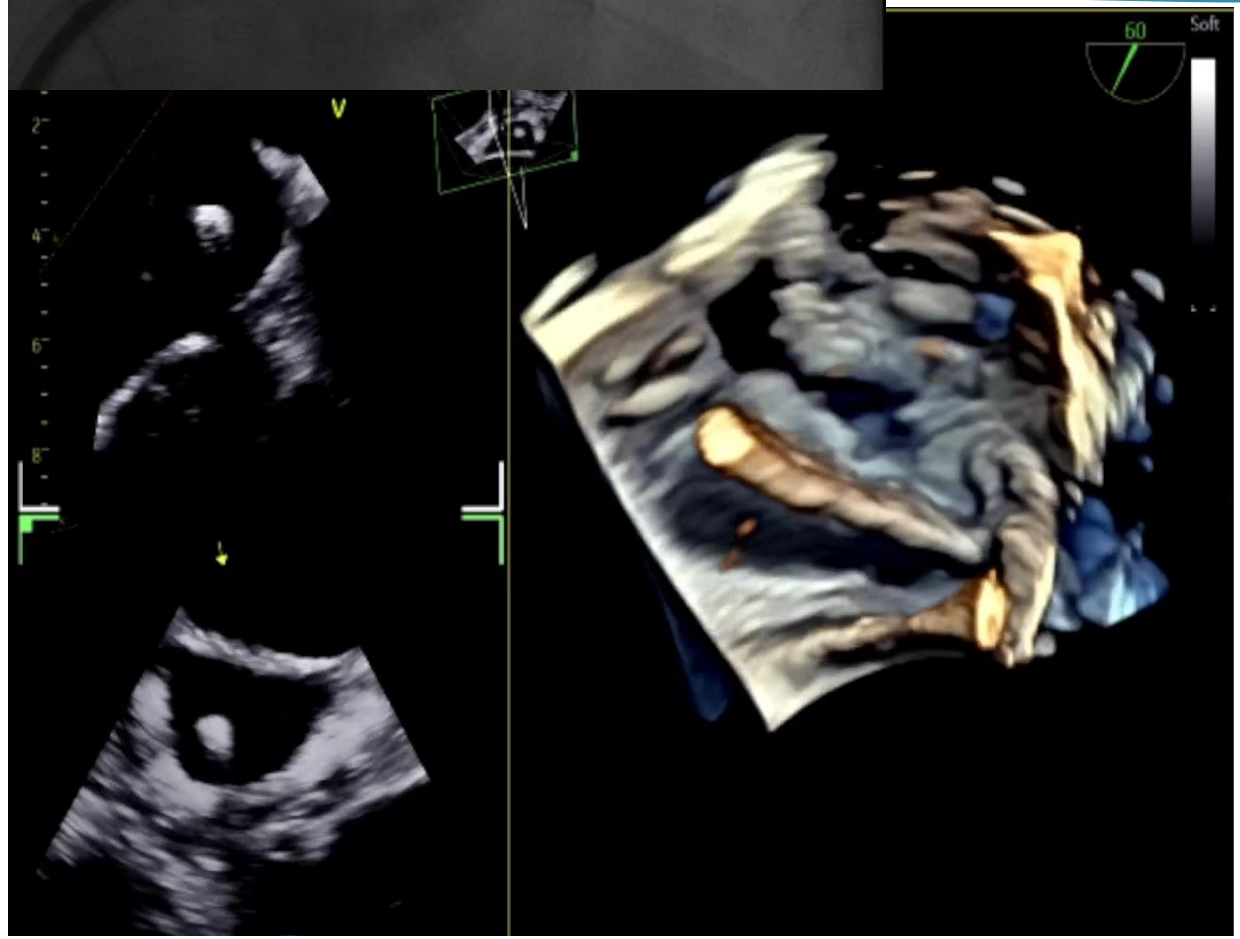


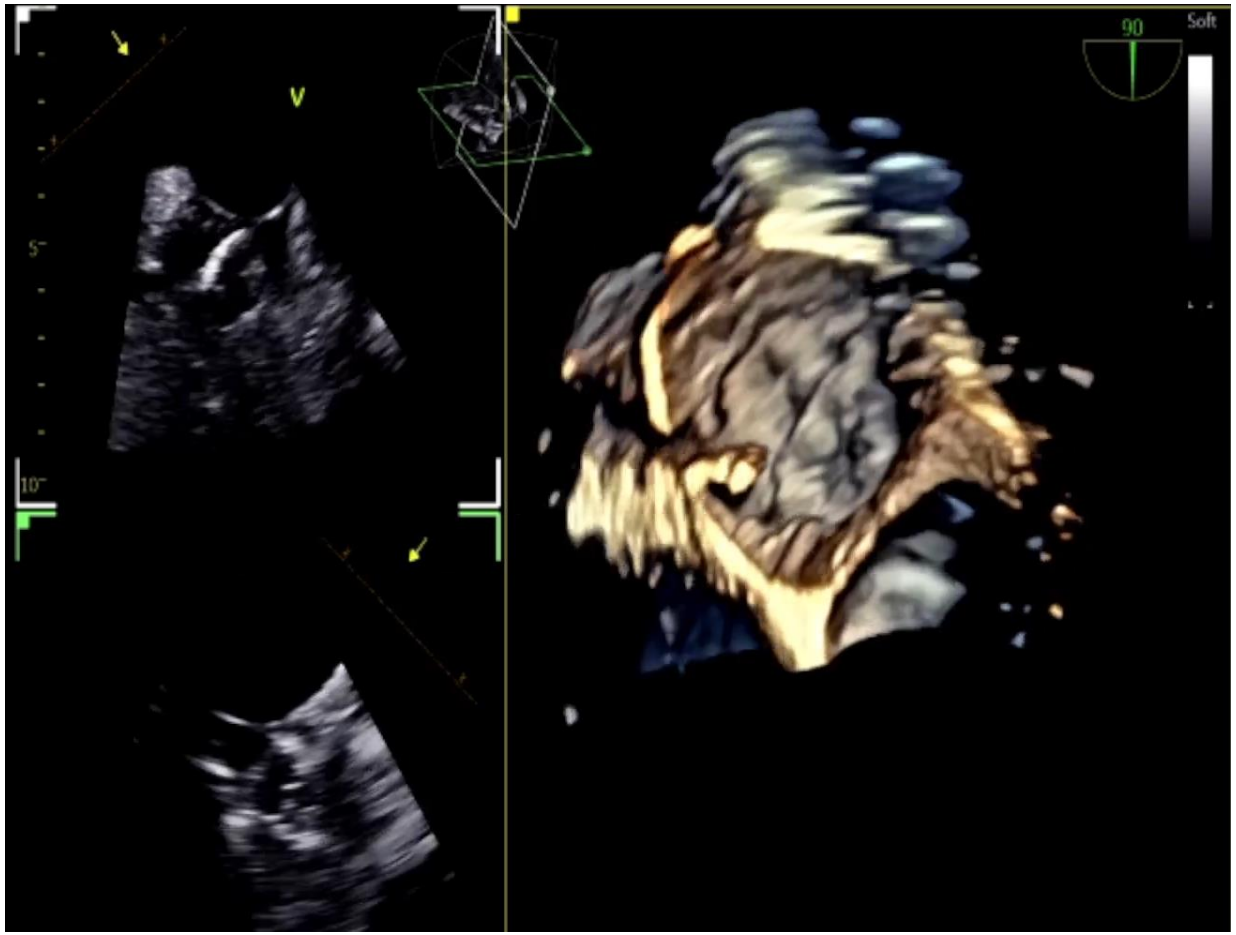
HONG KONG VALVES
HEART TEAM CONFERENCE

LAAO under Mini 4D TEE Probe [GE 9VT-D]



Local Anesthesia/Mini TEE [GE 9VT-D] LAAO LAmbre





Case Report
Interventional

Left Atrial Appendage Closure with 9VT-D, mini 4D TEE probe

Courtesy of Dr. Marta Sitges and Dr. Laura Sanchis, Hospital Clinic Barcelona, Spain

Patient History/ Pathology

68-year-old man was admitted due to heart failure after new-onset rapid atrial fibrillation (AF). Despite having a previous episode of paroxysmal AF, oral anticoagulation had been suspended after recurrent hematuria (chronic cystitis resulting from a previous radiotherapy treatment for prostate carcinoma). A transesophageal echocardiography (TEE) was performed to rule out thrombus before electric cardioversion. The patient was discharged with low-dose subcutaneous heparin and, after another episode of hematuria, percutaneous left atrial appendage (LAA) occlusion (LAAO) was proposed.

Challenges

Percutaneous LAAO needs planning with a 3D imaging technique (CT or TEE). Our patient had a previous TEE but without 3D measurements of the LAA and dedicated evaluation. Performing a new imaging test would have implied a delay in treatment as well as additional cost and risk (radiation, esophageal intubation). Alternatively, LAAO with general anesthesia and 3D TEE guiding had to be performed to evaluate the LAA and guide the procedure.

System, probe & device used

As we had available the 9VT-D mini TEE probe with 3D capabilities with the Vivid E95 (206 release) echocardiographic system, we decided to perform LAAO under conscious sedation and on an ambulatory basis with same day hospital discharge. The patient was admitted in the morning, LAAO was performed under conscious sedation and after 6 hours monitoring and a transthoracic echocardiography to rule out pericardial effusion and device embolization, the patient was discharged from the hospital.

Step-by-step procedure

The tolerance of the probe was excellent with only pharyngeal topic lidocaine and conscious sedation (fentanyl 0.05 mg and midazolam 2 mg). 3D measurements of the LAA (ostium 14x23 mm and landing zone 16x21 mm) were performed during LAAO with live MPR and an Amplatzer Amulet 25-mm device was chosen for closure. Transseptal puncture and device implantation were guided with biplane 3D imaging with a successful implantation.

Conclusion

The use of a mini TEE probe with 3D capabilities (9VT-D) allowed us to directly perform a safe and effective LAAO with conscious sedation and same day hospital discharge. Without this probe it would have been necessary to do a previous 3D imaging technique (TEE or CT) or to perform LAAO with general anesthesia and 3D TEE guiding with the standard probe.

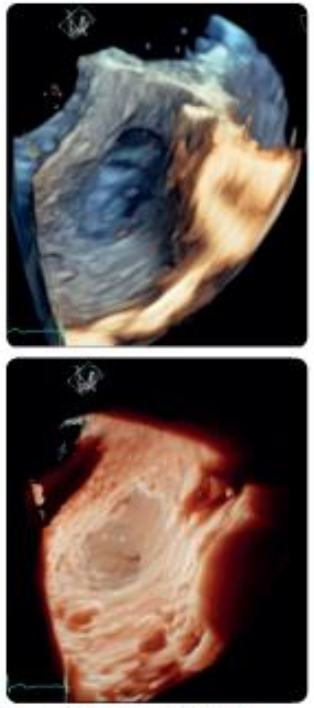


Figure 1. 3D visualization of the LAA ostium.

3D measurement of LAA

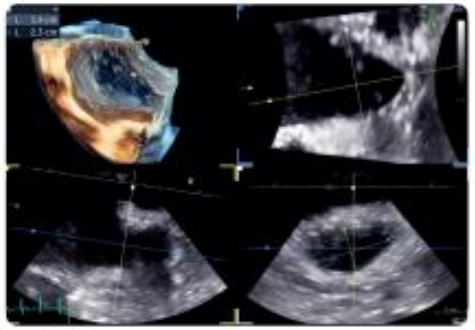


Figure 2. Ostium.

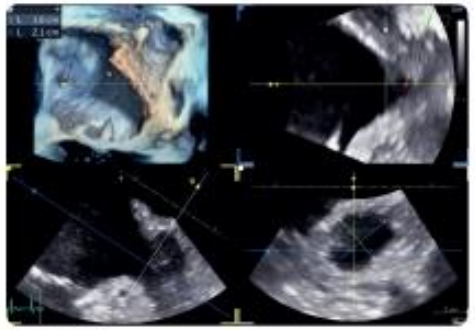


Figure 3. Landing zone.

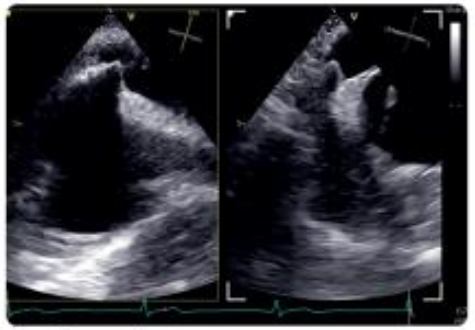


Figure 4. Transseptal puncture.

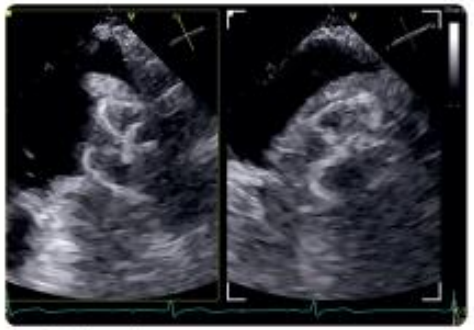


Figure 5. Lobe opening.

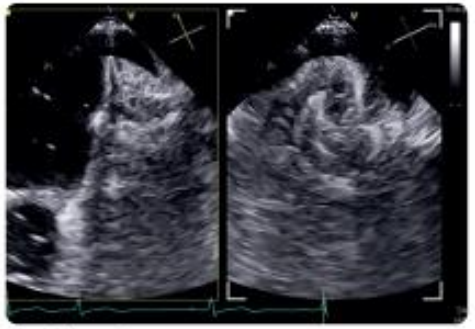


Figure 6. Disc opening.

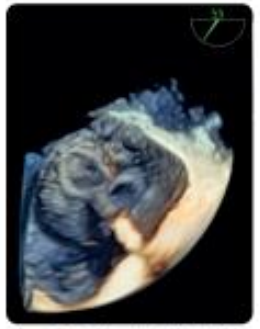


Figure 7. 3D evaluation of leaks before release.

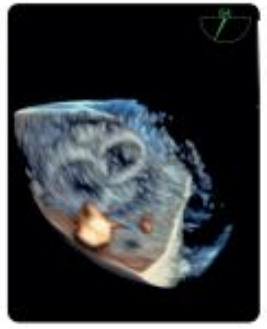


Figure 8. Final result.

9VT-D probe is exclusively available for Vivid E95 and Vivid E90 systems. Vivid Ultra Edition is released as of 25th August 2022. Ultra Edition is not a product name, it refers to the 2022 release of the Vivid portfolio.

Doctors are paid consultants for GEHC and were compensated for participation in this article. The statements described here are based on their own opinions and on results that were achieved in their unique setting. Since there is no "typical" hospital and many variables exist, i.e. hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results.

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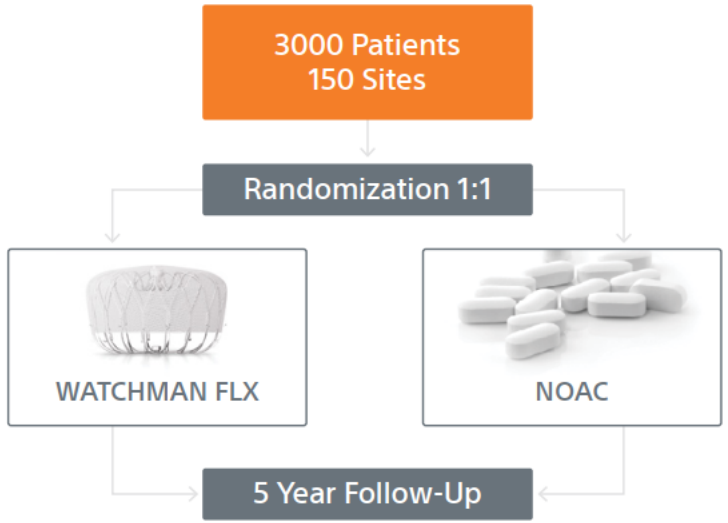
Ongoing Clinical Trials

CHAMPION-AF: Study Objective and Design

OBJECTIVE

The primary objective of the CHAMPION-AF Trial is to determine if left atrial appendage closure with the **WATCHMAN FLX™ LAAC Device** is a reasonable alternative compared with non-vitamin K oral anticoagulants (NOACs) in patients with non-valvular atrial fibrillation.

DESIGN



SH-1553805-AB

CATALYST Study

INVESTORS NEWSROOM RESPONSIBILITY LIVE HEALTHY

Abbott CONSUMERS HEALTHCARE PROFESSIONALS CAREERS ABOUT ABBOTT SEARCH

HOME > NEWSROOM > PRESS RELEASES

BACK TO PRESS RELEASES

ABBOTT ANNOUNCES FIRST-OF-ITS-KIND TRIAL TO ASSESS NEW THERAPY OPTION FOR PEOPLE AT RISK OF STROKE

- The CATALYST trial will examine Abbott's Amplatzer™ Amulet™ device compared to non-vitamin K oral anticoagulants, the current standard in attempting to lower stroke and bleeding risks for patients with atrial fibrillation

Photos (1)

ABBOTT PARK, Ill., Feb. 3, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the U.S. Food and Drug Administration (FDA) has approved a new trial designed to assess its Amplatzer™ Amulet™ Left Atrial Appendage Occluder for people with atrial fibrillation (AF) – a condition in which the normal rhythm of the heart's upper chambers is disrupted and becomes erratic – who are at risk of stroke. The CATALYST trial is the first-ever clinical trial comparing the effectiveness of a

ELSEVIER

American Heart Journal

Volume 251, September 2022, Pages 35-42

Trial Designs

Comparison of anticoagulation with left atrial appendage closure after atrial fibrillation ablation: Rationale and design of the OPTION randomized trial

Oussama M. Wazni MD [a], Lucas Boersma MD [b], Jeff S. Healey MD [c], Moussa Mansour MD [d], Claudio Tondo MD [e], Karen Phillips MBBS [f],

OPTION Trial[1]

OBJECTIVE:

To determine if LAAC with the WATCHMAN FLX™ Left Atrial Appendage Closure Device is a reasonable alternative to oral anticoagulation following catheter ablation for patients with NVAF.

1600 randomized subjects at 130 sites world-wide (enrollment completed)
Randomized 1:1 (Device to OAC)
Follow-Up at 3, 12, 24, and 36 months

MEDICATION REGIMENS

Device Group
Market approved OAC and aspirin (75-100mg recommended) for 90 days followed by aspirin through at least 12-months post-implant (recommended for duration of the trial).

Control (OAC) Group
Market approved OAC used per IFU for atrial fibrillation stroke prevention for the duration of the trial.

PRIMARY ENDPOINTS

Non-inferiority: All cause death, stroke, SE through 36 months
Superiority: Major non-procedural bleeding through 36 months

1 Study protocol, manuscript in development for publication.

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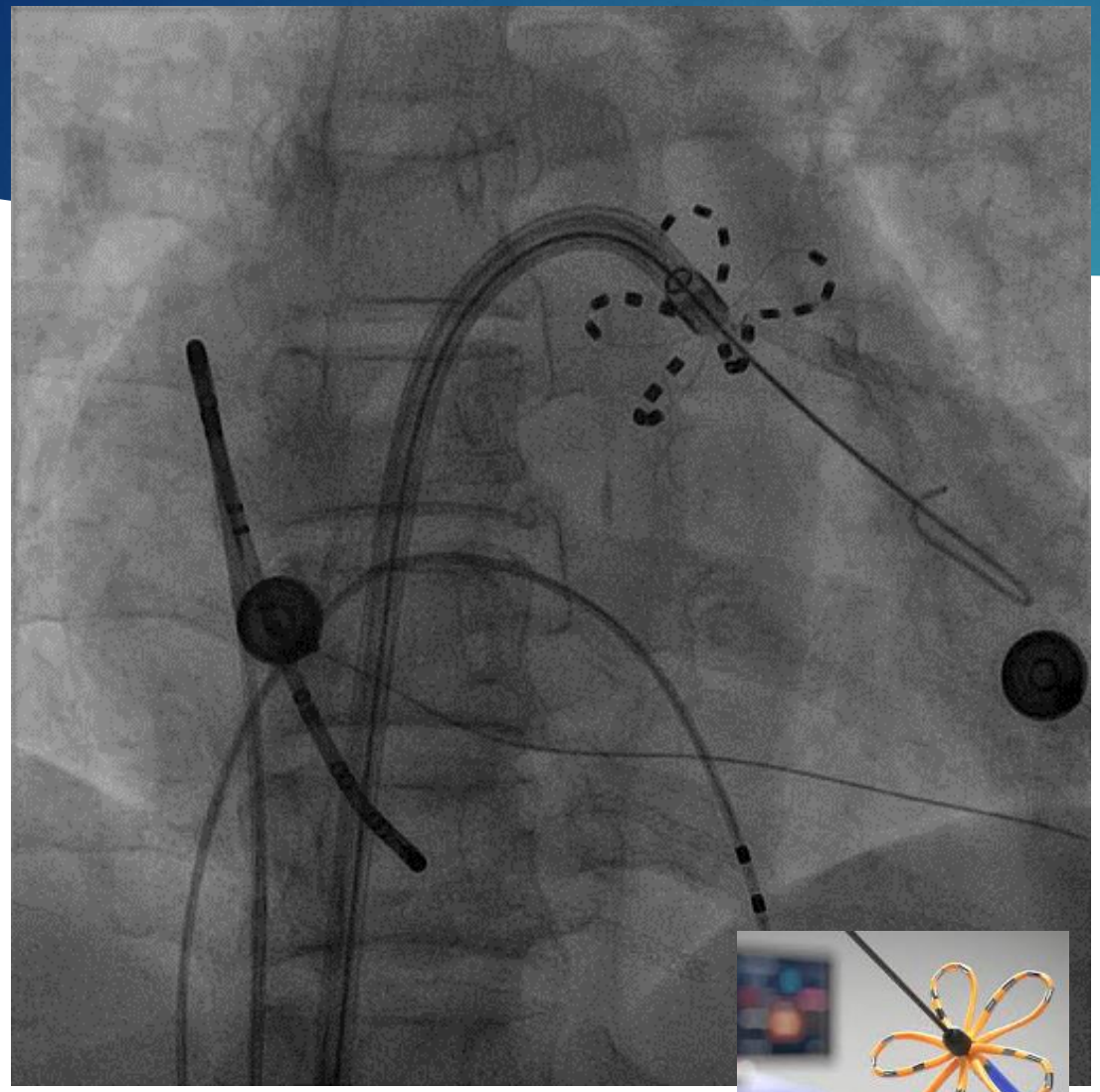
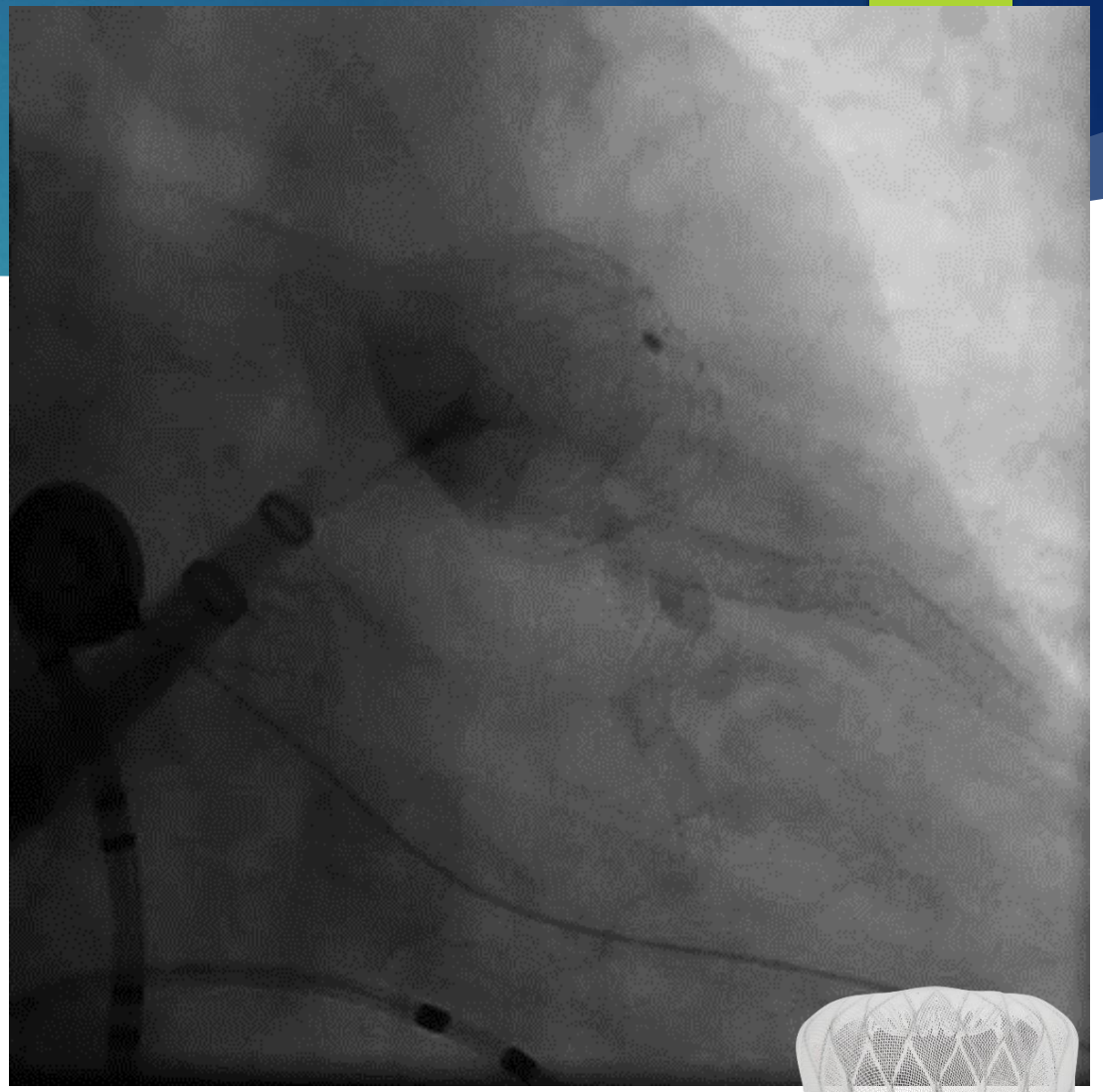
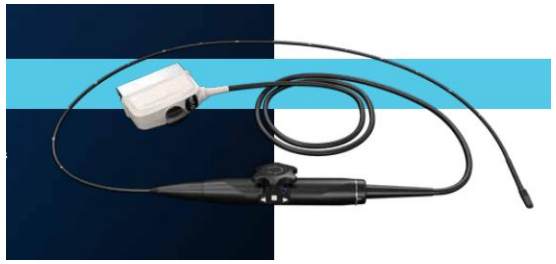




Conclusion

- Evolving technologies for LAA Closure
- New Concepts for Closure/LAA Exclusion
- Streamline of Implantation Planning
- Overcoming technical challenges and unresolved issues associated with the LAA Closure
- On-going clinical trials



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