

# LAA Closure with **AMULET** and **LAmbre Device**

TCTAP 2023 7/5/2023 Sunday 7:00am to 8:00am  
Presentation Theater 1, Vista 3, B2

**HKU  
Med**

**Simon Lam** MBBS (HK) MRCP (UK) FRCP (Edin, Glas) FACC FESC  
Queen Mary Hospital, The University of Hong Kong

# Disclosure

- Conflict of Interest – Nothing for Disclosure

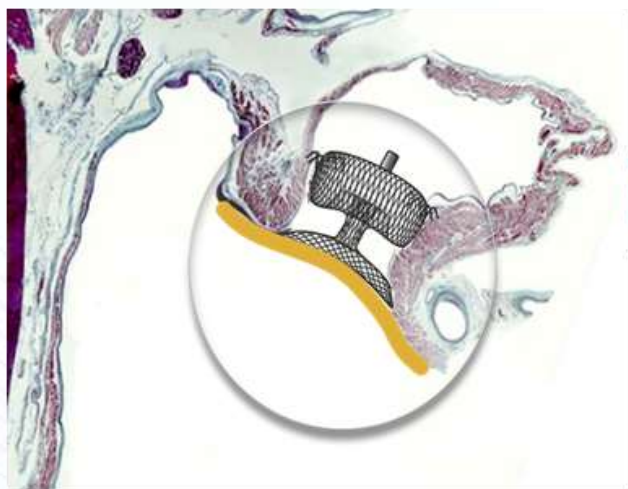
# AMULET

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# Abbott AMULET

## Left Atrial Appendage Occlusion Device

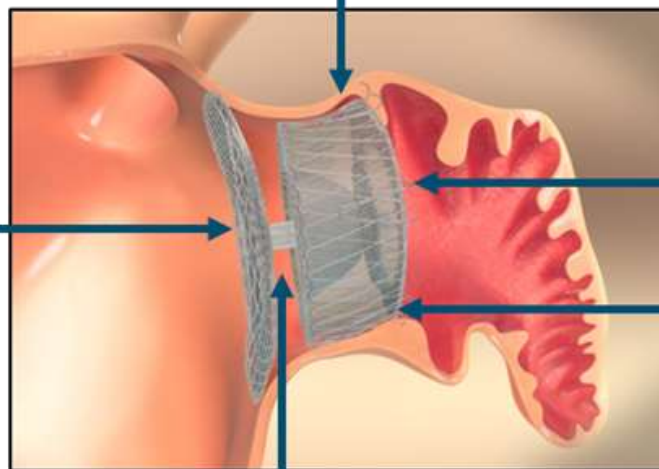


### Disc

- 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

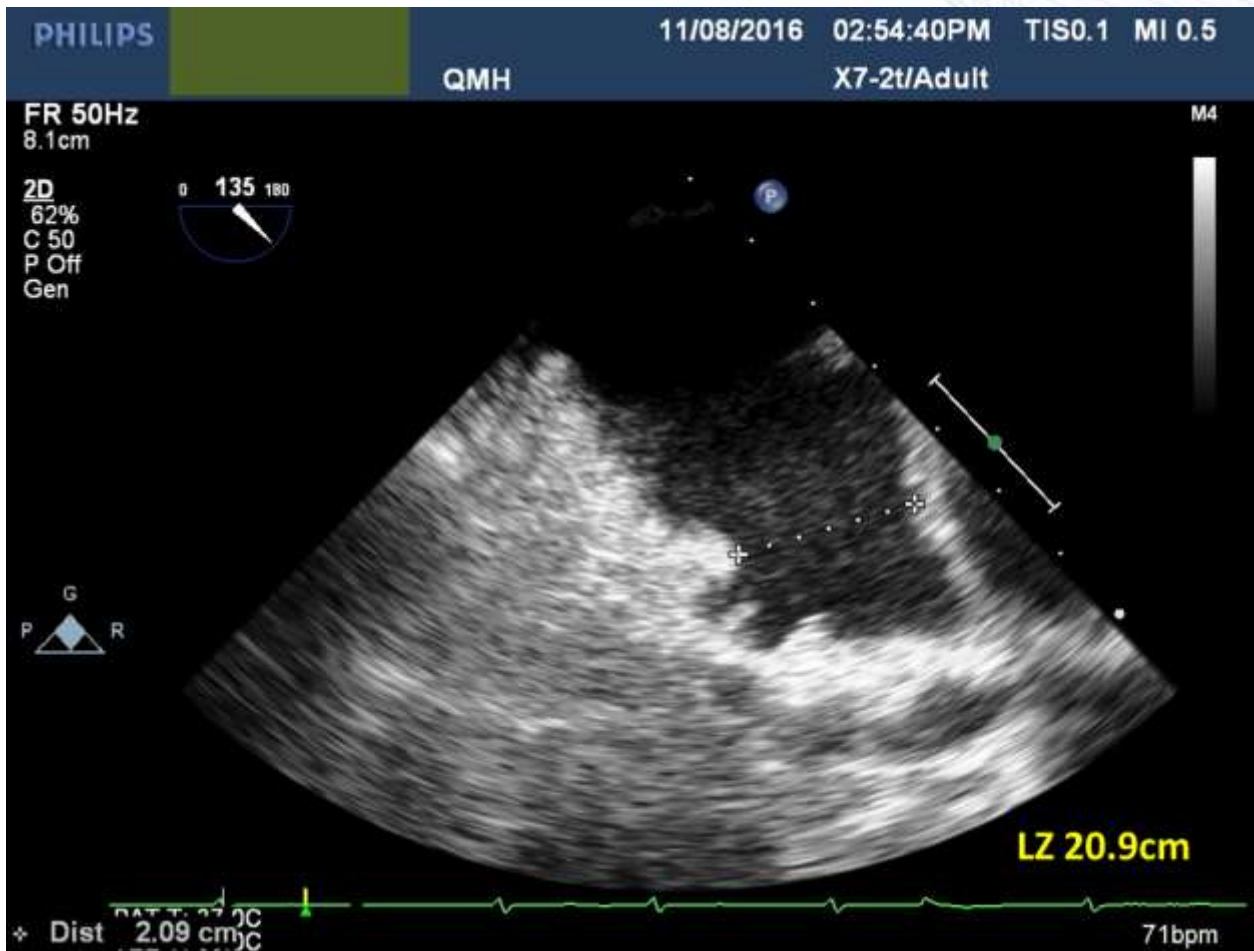
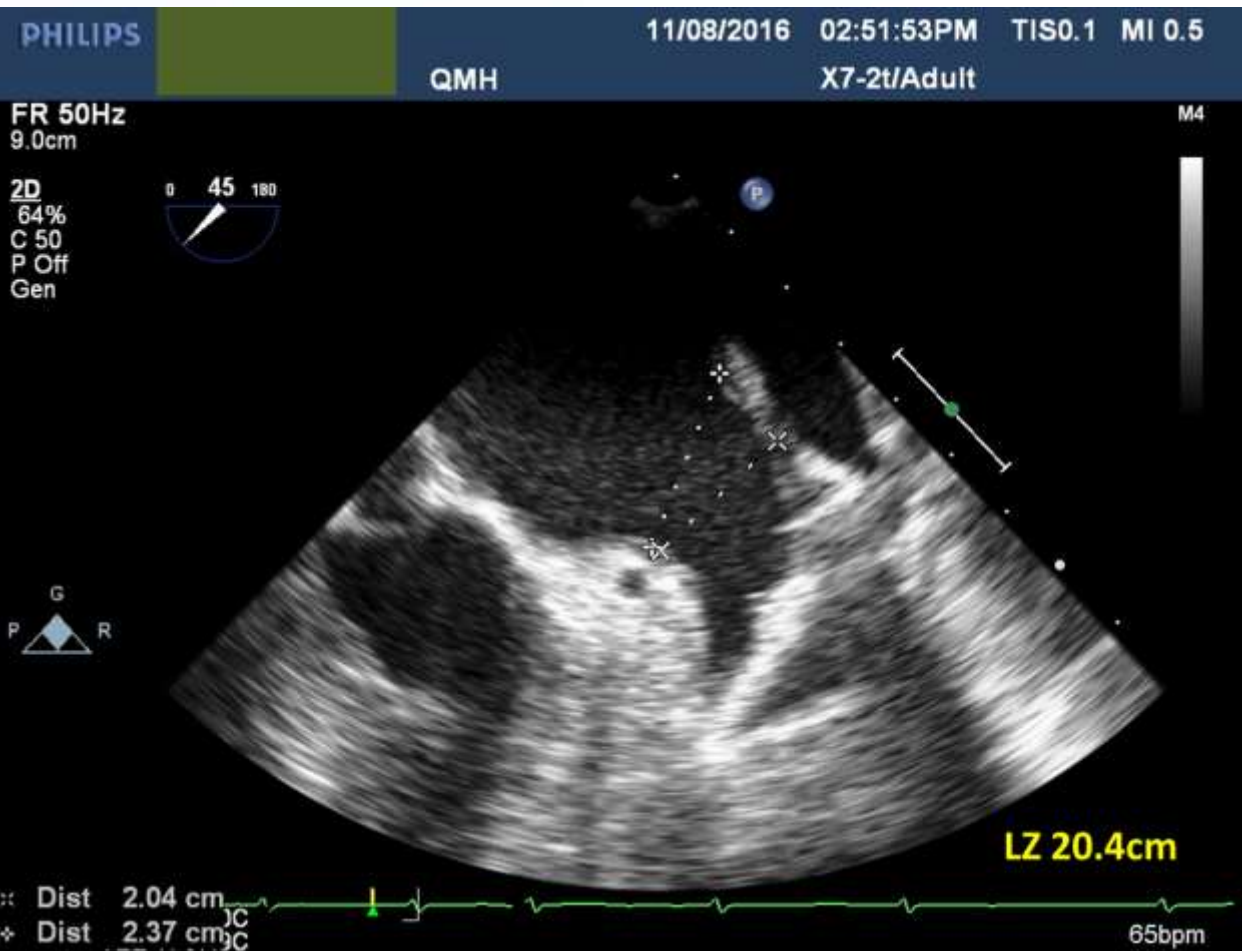


### Stabilizing Wires

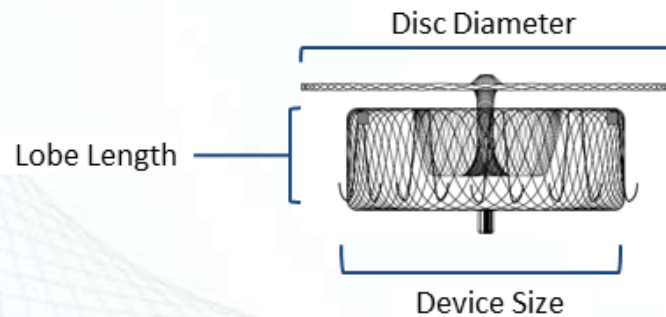
- **Engage** with the wall of the LAA
- **Help** hold the device in place

### Waist

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



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	



## Device Size Selection - Amulet



Im: 1/150

Se: 1

QUEEN MARY HOSPITAL  
CG160232  
Cardiac Special  
Fluoroscopy

WL: 128 WW: 256 [D]

AP

11/8/2016 15:19:17

PHILIPS

11/08/2016 03:22:34PM TIS0.3 MI 0.6

X7-2t/Adult

FR 50Hz  
9.0cm

2D  
61%  
C 50  
P Off  
HGen



JPEG

61 bpm

PAT T: 37.0C  
TEE T: 40.1C

Im: 24/107  
Se: 1

QUEEN MARY HOSPITAL  
CG160232  
Cardiac Special  
Fluoroscopy

WL: 128 WW: 256 [D]  
RAO: 30 CRA: 20

11/8/2016 15:20:40

PHILIPS 11/08/2016 03:23:58PM TIS0.3 MI 0.6  
X7-2t/Adult

FR 50Hz  
8.1cm

2D  
60%  
C 50  
P Off  
HGen

0 28 180

M4

P

2.7 6.4

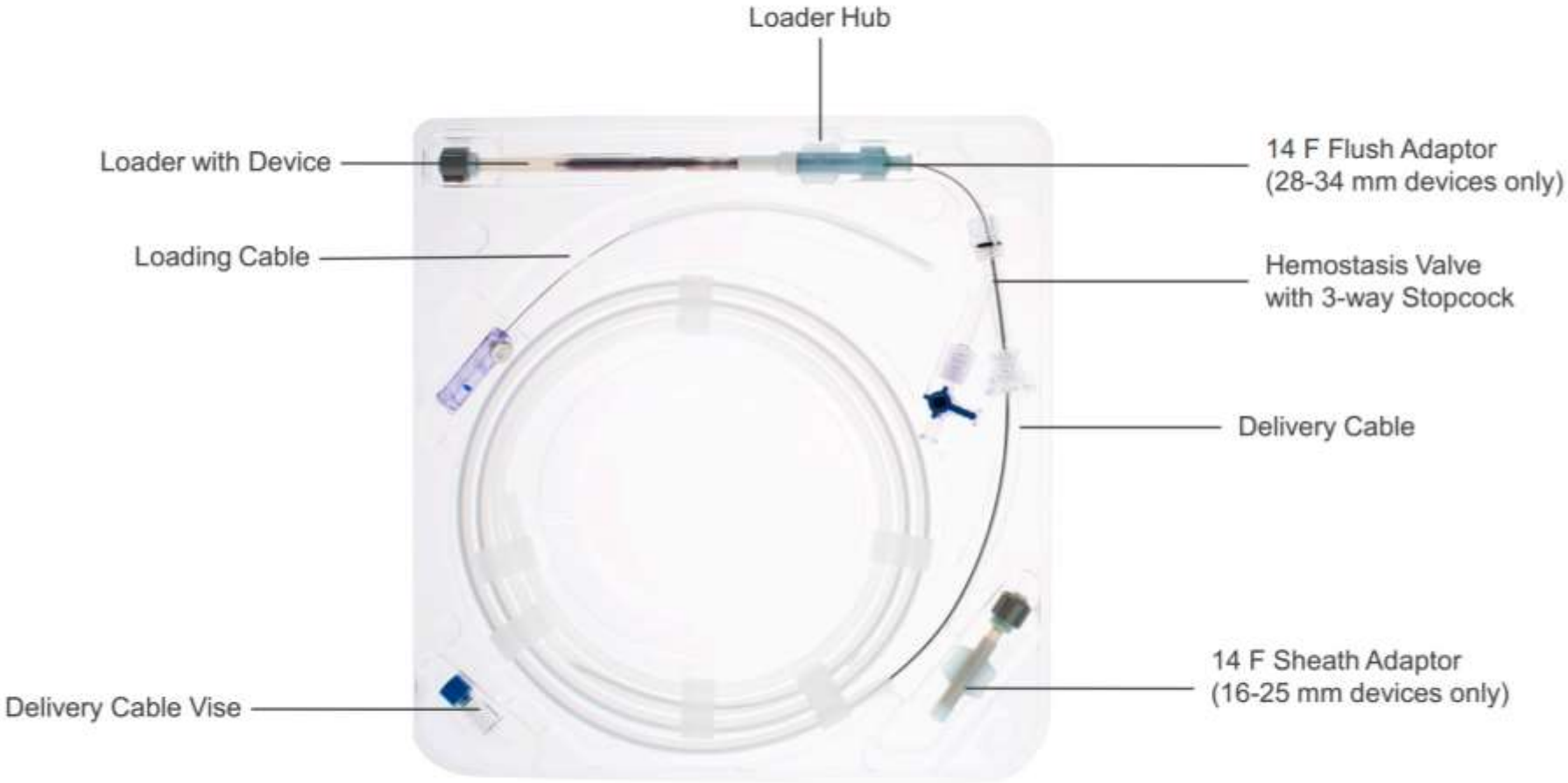
JPEG

PAT T: 37.0C  
TEE T: 39.7C

54 bpm



# Device Package Components

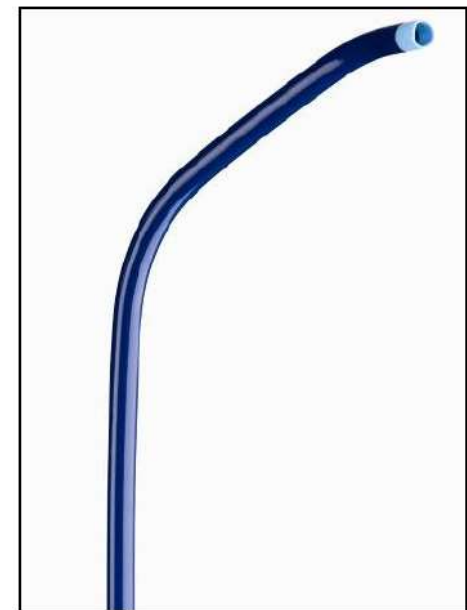


Im: 1/150  
Se: 1

QUEEN MARY HOSPITAL  
CG160232  
Cardiac Special  
Fluoroscopy

WL: 128 WW: 256 [D]  
RAO: 30

11/8/2016 15:37:42



**AMPLATZER™**  
**TorqVue™ 45°x 45°**  
**Delivery System**

Im: 1/21  
Se: 1

QUEEN MARY HOSPITAL  
CG160232  
Cardiac Special  
Fluoroscopy

WL: 128 WW: 256 [D]  
RAO: 30

11/8/2016 15:37:58

Im: 1/41  
Se: 1

QUEEN MARY HOSPITAL  
CG160232  
Cardiac Special  
Fluoroscopy

WL: 128 WW: 256 [D]  
RAO: 30 CAU: 20

11/8/2016 15:39:42

AMULET 25mm





Im: 1/48  
Se: 1

QUEEN MARY HOSPITAL  
CG160232  
Cardiac Special  
Fluoroscopy

WL: 128 WW: 256 [D]  
RAO: 30 CAU: 20

11/8/2016 15:40:5





Im: 1/12  
Se: 1

QUEEN MARY HOSPITAL  
CG160232  
Cardiac Special  
Fluoroscopy

WL: 128 WW: 256 [D]  
RAO: 30 CAU: 20

11/8/2016 15:41:2



Im: 1/39  
Se: 1

HUNG  
4255  
159 M  
QUEEN MARY HOSPITAL  
CG160232  
Cardiac Special  
Fluoroscopy

WL: 128 WW: 256 [D]  
RAO: 30 CAU: 20

11/8/2016 15:41:

PHILIPS 11/08/2016 03:48:05PM TISO.3 MI 0.6  
X7-2t/Adult

FR 50Hz  
10cm

2D  
66%  
C 50  
P Off  
HGen

74 mm

M4

P 2.7 R 6.4

JPEG

PAT T: 37.0C  
TEE T: 39.8C

60 bpm



Im: 1/150  
Se: 1

HUNG  
4255  
59 M

QUEEN MARY HOSPITAL  
CG160232  
Cardiac Special  
Fluoroscopy

WL: 128 WW: 256 [D]  
RAO: 30 CAU: 20

11/8/2016 15:42:28

AMULET 25mm





Im: 1/9  
Se: 1

QUEEN MARY HOSPITAL  
CG160232  
Cardiac Special  
Fluoroscopy

WL: 128 WW: 256 [D]  
RAO: 30 CAU: 20

11/8/2016 15:43:09

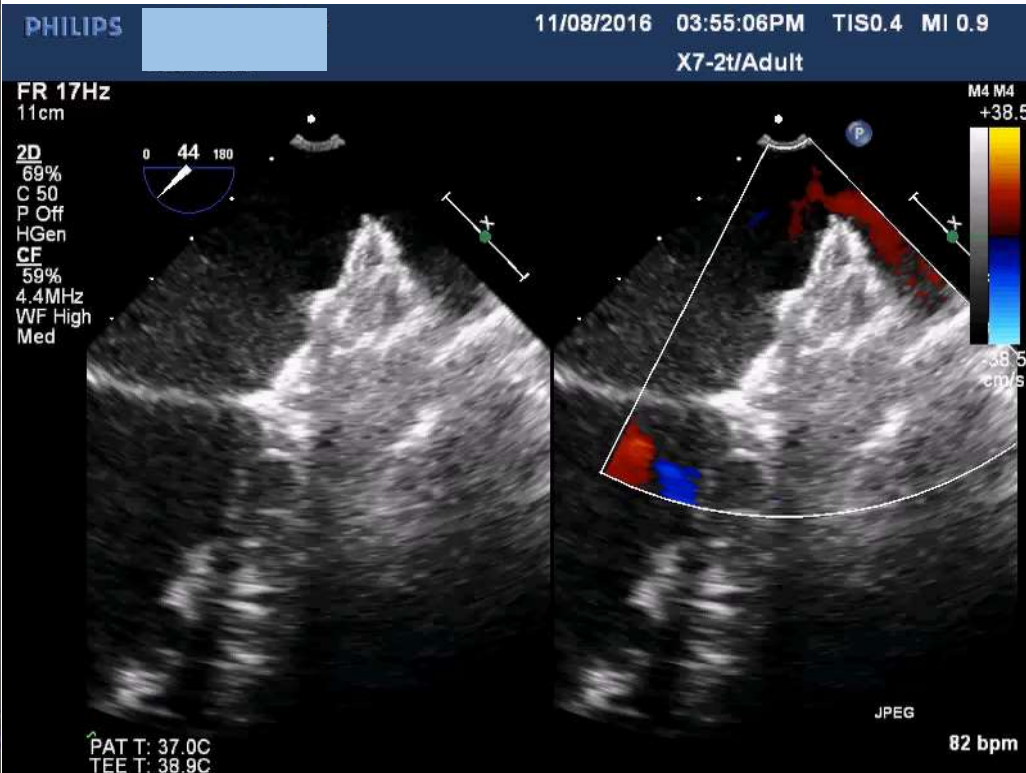


Im: 1/56  
Se: 1

QUEEN MARY HOSPITAL  
CG160232  
Cardiac Special  
Fluoroscopy

WL: 128 WW: 256 [D]  
RAO: 30 CAU: 20

11/8/2016 15:48:00





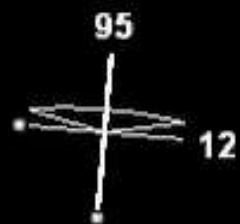
FR 10Hz  
11cm

xPlane

68%  
68%  
50dB  
P Off  
HGen

CF

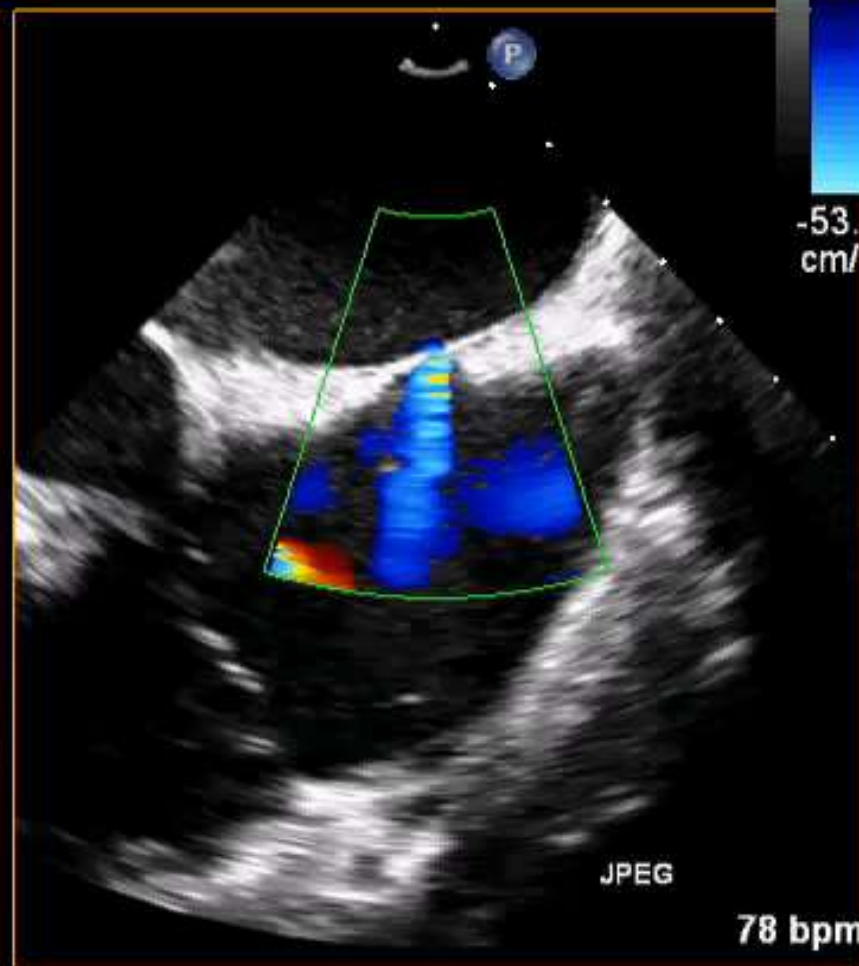
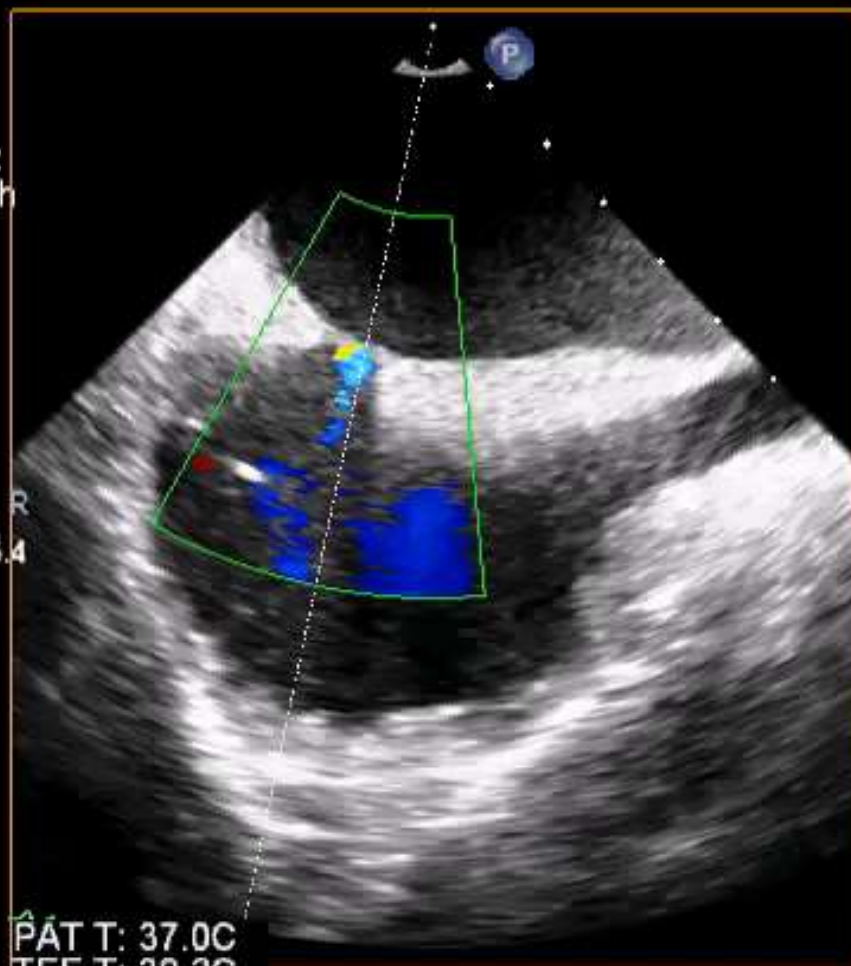
59%  
4.4MHz  
WF High  
Med



M4 M4  
+53.9



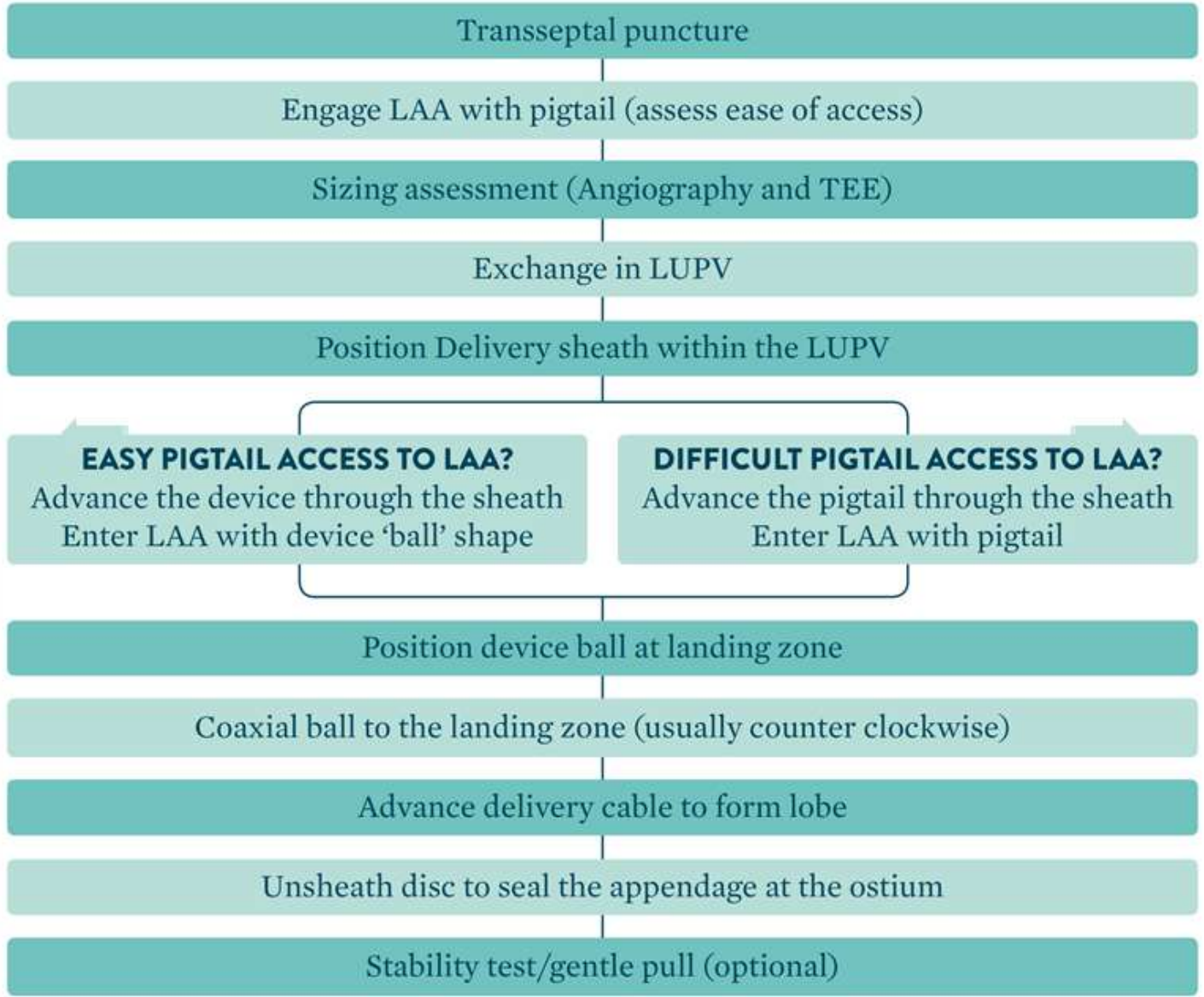
-53.9  
cm/s



JPEG

78 bpm

PAT T: 37.0C  
TEE T: 39.2C



# LAA Occlusion with the Amplatzer™ Amulet™ device: Primary results of the prospective global Amulet Observational Study

Dr. David Hildick-Smith, MD – Brighton and Sussex University Hospitals, Brighton, United Kingdom

Prof. Ulf Landmesser, MD – Charité – University Medicine, Berlin, Germany

Prof. John Camm, MD – St. George's University Hospital, and Imperial College, London, United Kingdom

Prof. Hans-Christoph Diener, MD, PhD – Universitätsklinikum Essen, Essen, Germany

Dr. Vince Paul, MD – Fiona Stanley Hospital, Perth, Australia

Dr. Boris Schmidt, MD – Cardioangiologisches Centrum Bethanien, Frankfurt, Germany

Prof. Magnus Settergren, MD, PhD – Karolinska Universitetssjukhuset Solna, Stockholm, Sweden

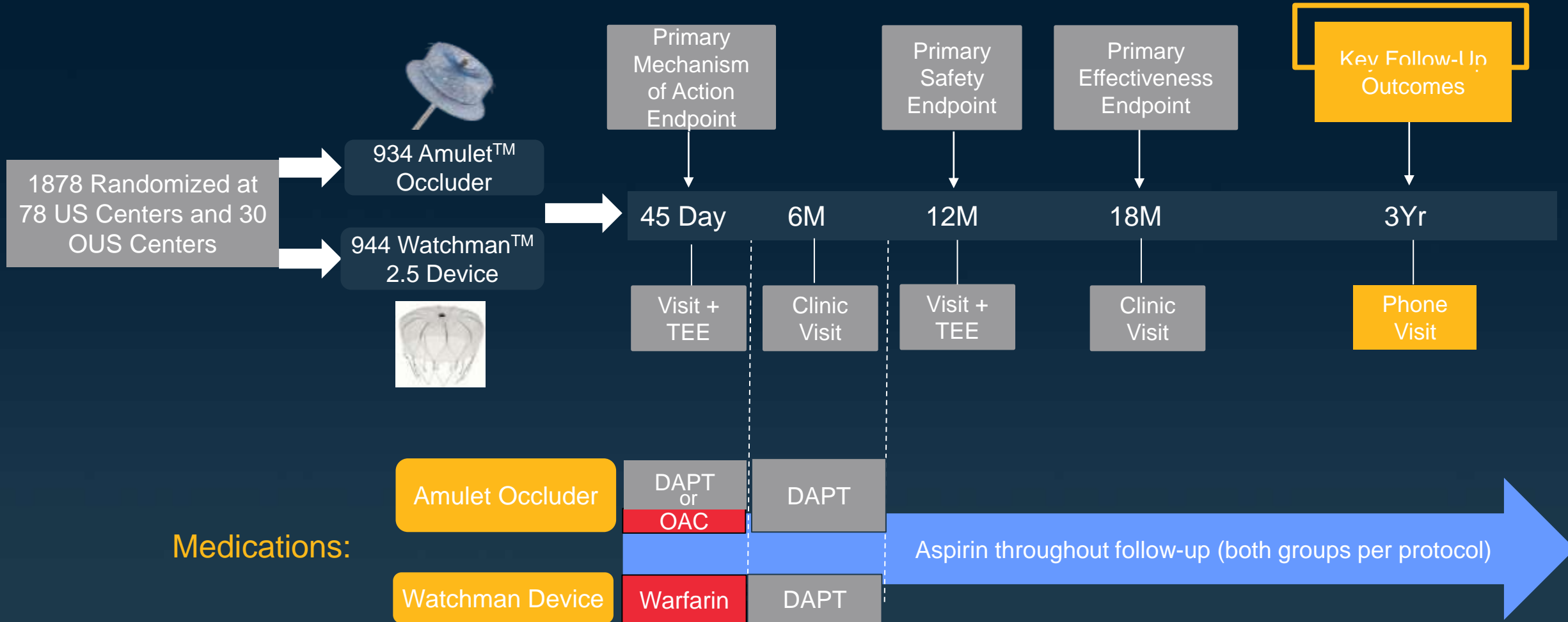
Prof. Emmanuel Teiger, MD, PhD – University Hospital Henri Mondor, Creteil, France

Prof. Jens Erik Nielsen-Kudsk, MD, DMSc – Aarhus University Hospital, Aarhus, Denmark

Prof. Claudio Tondo, MD, PhD – University of Milan, Milan, Italy

On Behalf of the Amulet Observational Study Investigators

# Amulet IDE Trial





# CATALYST Study

INVESTORS NEWSROOM RESPONSIBILITY LIVE HEALTHY



CONSUMERS

HEALTHCARE PROFESSIONALS

CAREERS

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SEARCH



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## 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



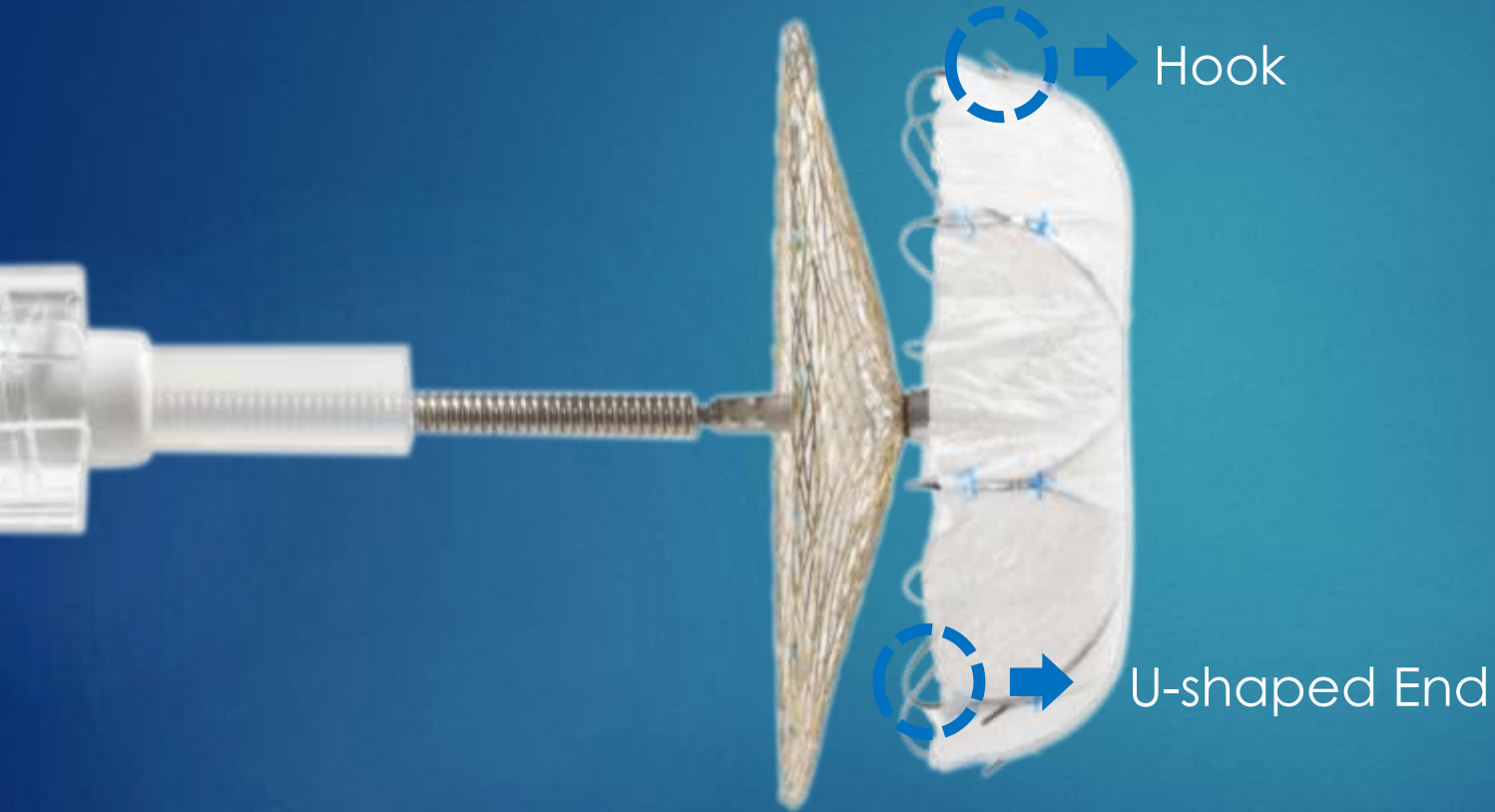
# Lambre

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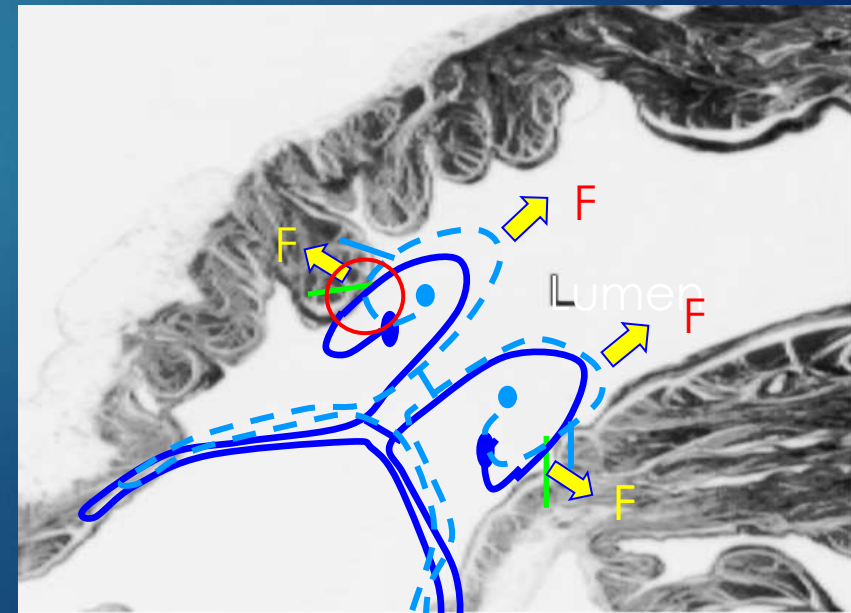
# Stable Device Fixation

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)



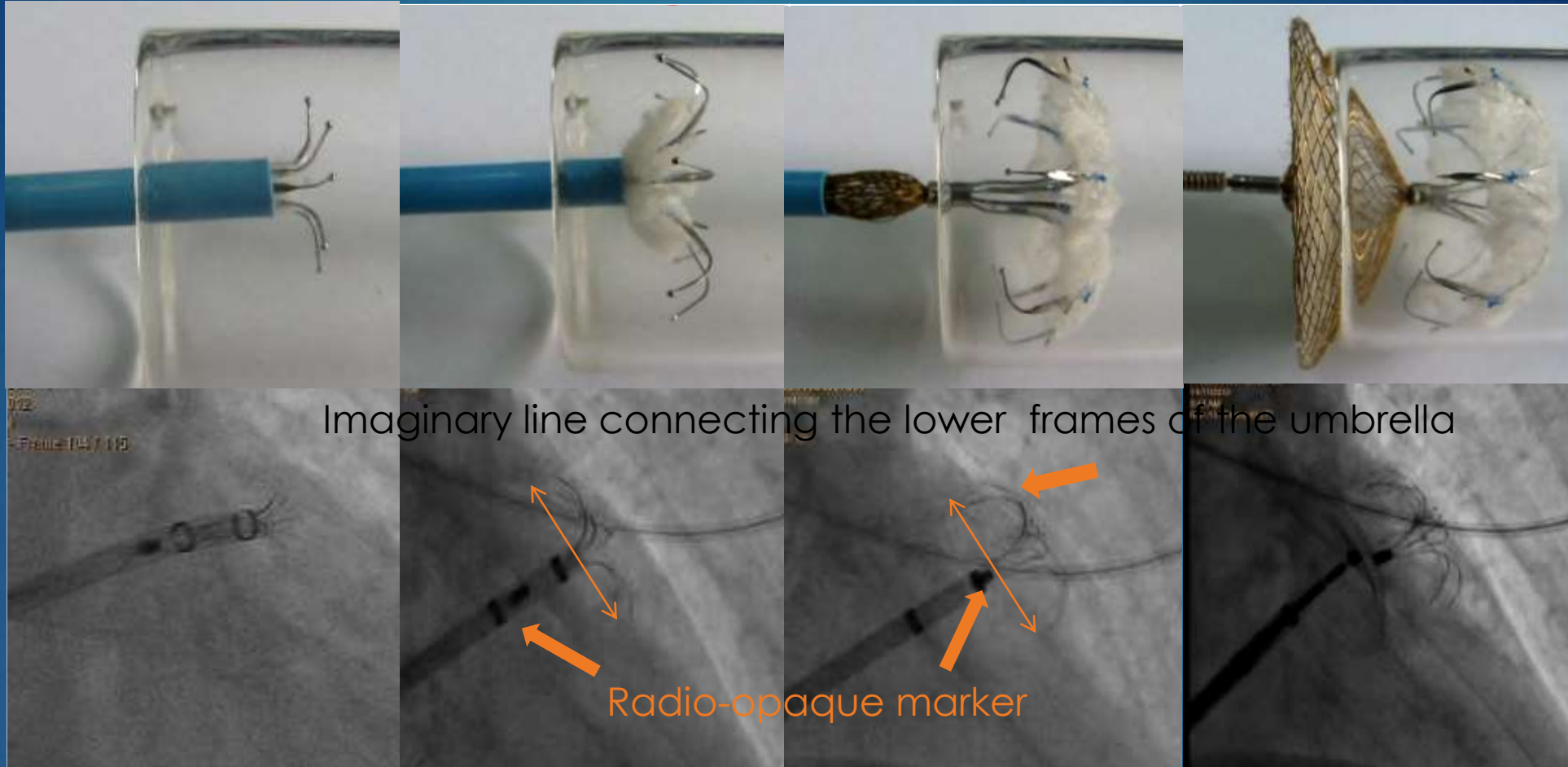
# Fully Retrievable/Repositionable

## Special design of the Umbrella

- Easily and fully retrievable/repositionable
- With less injury to LAA



# Fully Retrivable/Repositionable



Umbrella  
Just opened

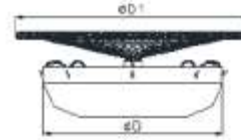
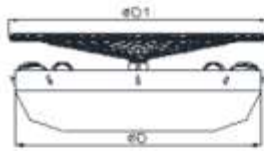
Umbrella  
PARTIALLY  
opened

Umbrella  
FULLY opened

LA cover  
Deployed



# 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
LT-LAA-1824	18	24	10F-900
LT-LAA-2026	20	26	9F-900
LT-LAA-2228	22	28	10F-900
LT-LAA-2430	24	30	
LT-LAA-2632	26	32	
LT-LAA-2834	28	34	
LT-LAA-3036	30	36	
LT-LAA-3236	32	36	10F-900
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	
LT-LAA-2032	20	32	
LT-LAA-2234	22	34	10F-900
LT-LAA-2436	24	36	
LT-LAA-2638	26	38	

LAA landing zone/ostium/depth measurement and Size Selection

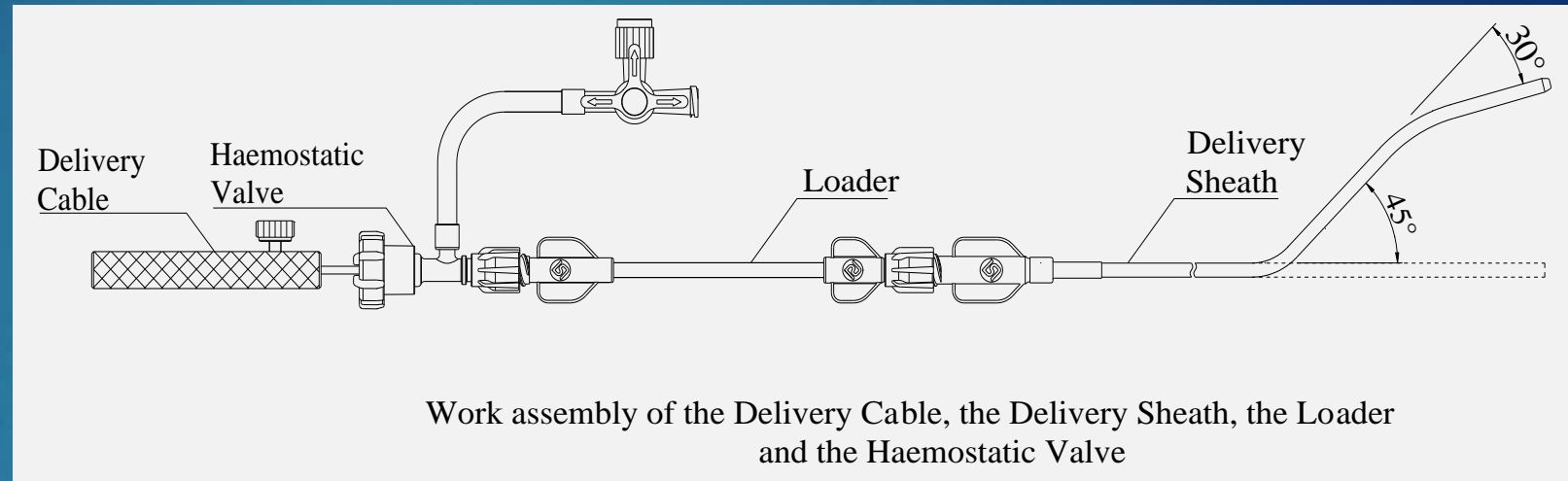
- Choose an Occluder 3-8mm larger than the measured landing zone;
- Selection of a Special-type Occluder (small umbrella with a relatively big cover) may be considered if the ostium is 10mm than landing zone)



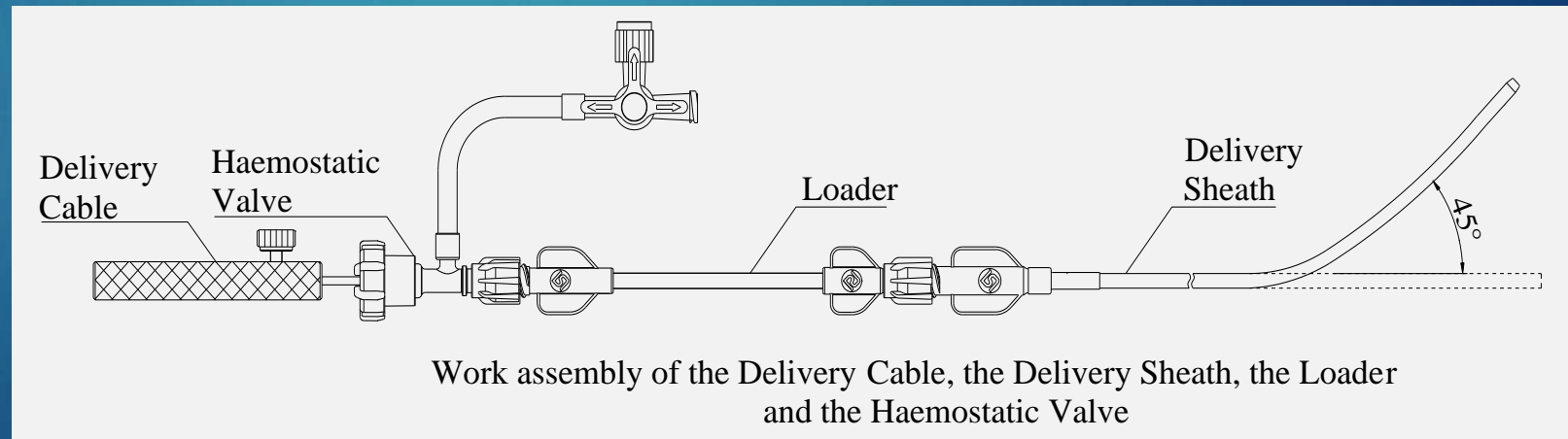
# Lambre™ LAA Closure System

Delivery system

45° x 30°  
Double  
Curved

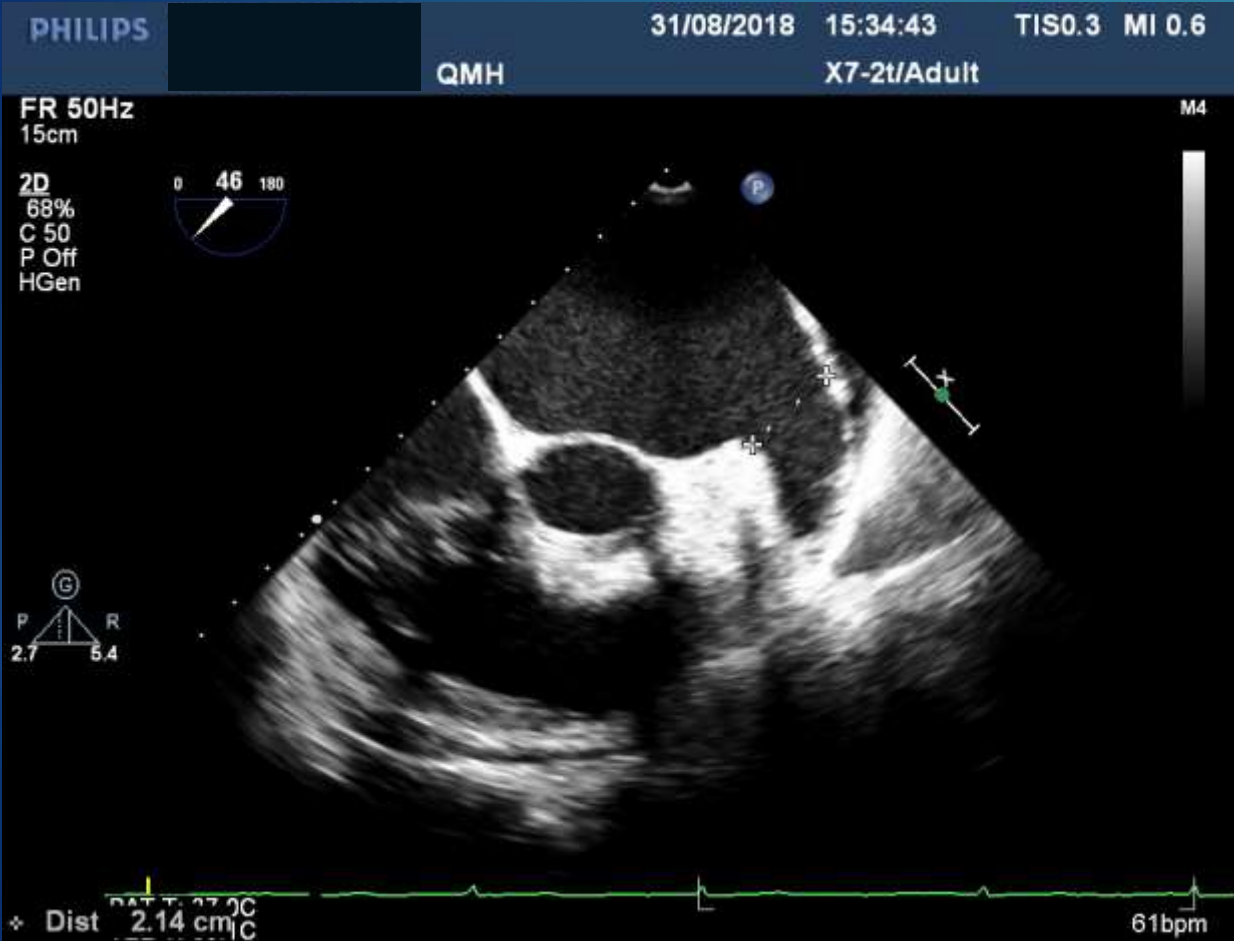


45°  
Single Curved





# ► Case Illustration 1



FR 50Hz  
12cm

M4

2D  
67%  
C 50  
P Off  
HGen



Ostium 32mm

Landing zone 20mm -22mm

Dist 2.02 cm

45bpm

# LAA closure

- ▶ ACIST injector – Disable mode
- ▶ 2D and 3D TEE + Fluoroscopic guidance
- ▶ 8.5Fr SL1 SJM Transseptal Sheath
- ▶ 89cm Baylis NRG Radiofrequency needle C1 curve (10W 2sec)
- ▶ 6Fr Pigtail
- ▶ 10 Fr Lambre 45 30 Delivery Sheath
- ▶ **Lambre #26 38mm**







Im: 1/19  
Se: 2



Queen Mary Hospital  
1141-2018  
XA  
Left Coronary 15 fps

WL: 129 WW: 190 [D]  
RAO: 30 CAU: 20

31/8/2018 4:11:41 PM

Im: 229/300  
Se: 4



Queen Mary Hospital  
1141-2018  
XA  
Fluoroscopy

WL: 115 WW: 213 [D]  
RAO: 30 CAU: 20

31/8/2018 4:15:19 PM

Im: 1/20  
Se: 6

24/12/1931 M  
Queen Mary Hospital  
1141-2018  
XA  
Left Coronary 15 fps

WL: 129 WW: 190 [D]  
RAO: 30 CAU: 20

31/8/2018 4:16:46 PM

Im: 72/228  
Se: 7

24/12/1931 M  
Queen Mary Hospital  
1141-2018  
XA  
Fluoroscopy

WL: 115 WW: 213 [D]  
RAO: 30 CAU: 20

31/8/2018 4:16:59 PM

Im: 1/9  
Se: 8

24/12/1931 M  
Queen Mary Hospital  
1141-2018  
XA  
Left Coronary 15 fps



WL: 129 WW: 190 [D]  
RAO: 30 CAU: 20

31/8/2018 4:17:30 PM

FR 29Hz  
14cm

M4

xPlane  
61%  
61%  
50dB  
P Off  
HGen



PAT T: 37.0C  
TEE T: 39.5C

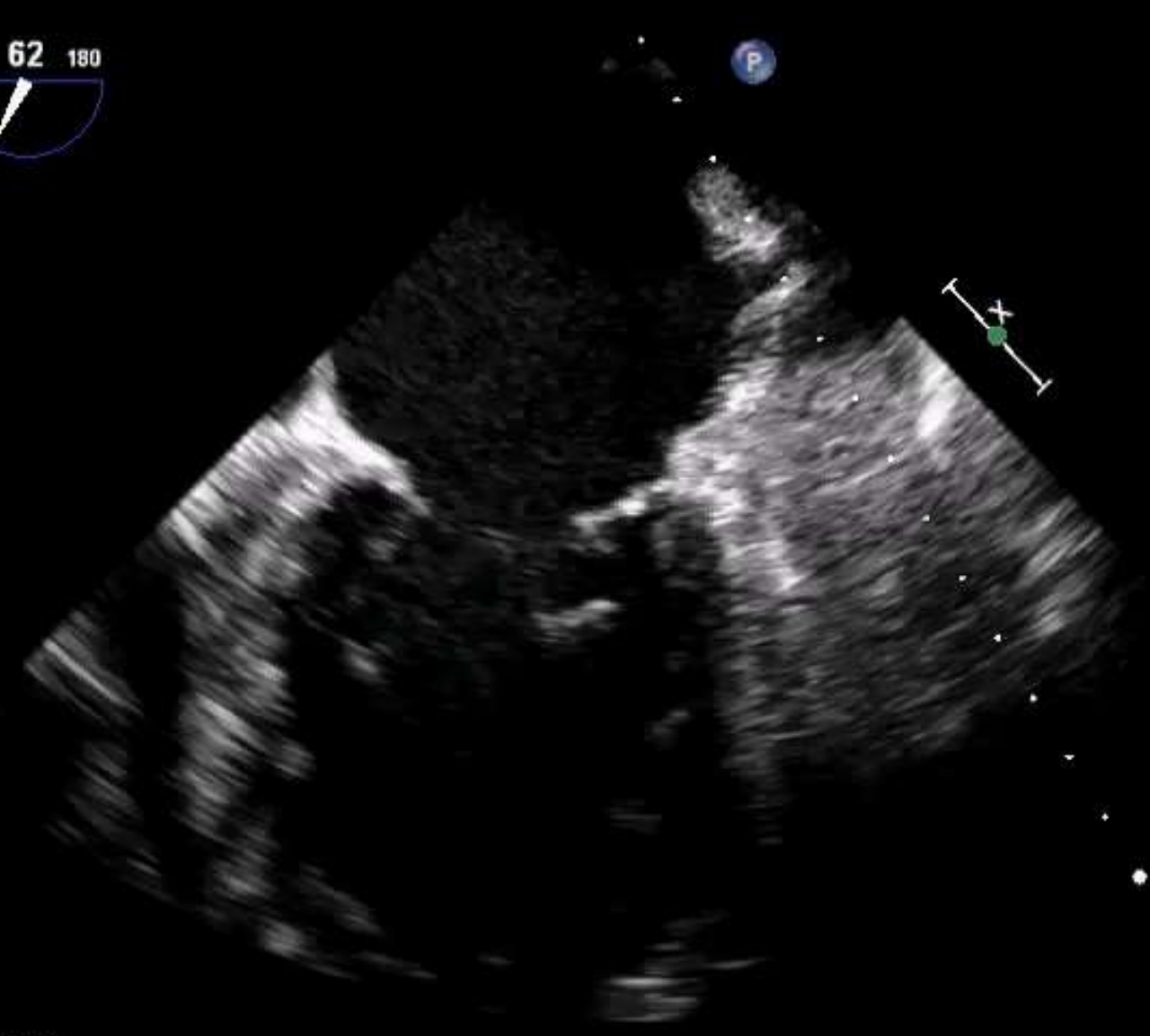
77 bpm



FR 50Hz  
14cm

M4

2D  
61%  
C 50  
P Off  
HGen



JPEG

PAT T: 37.0C  
TEE T: 39.4C

58 bpm

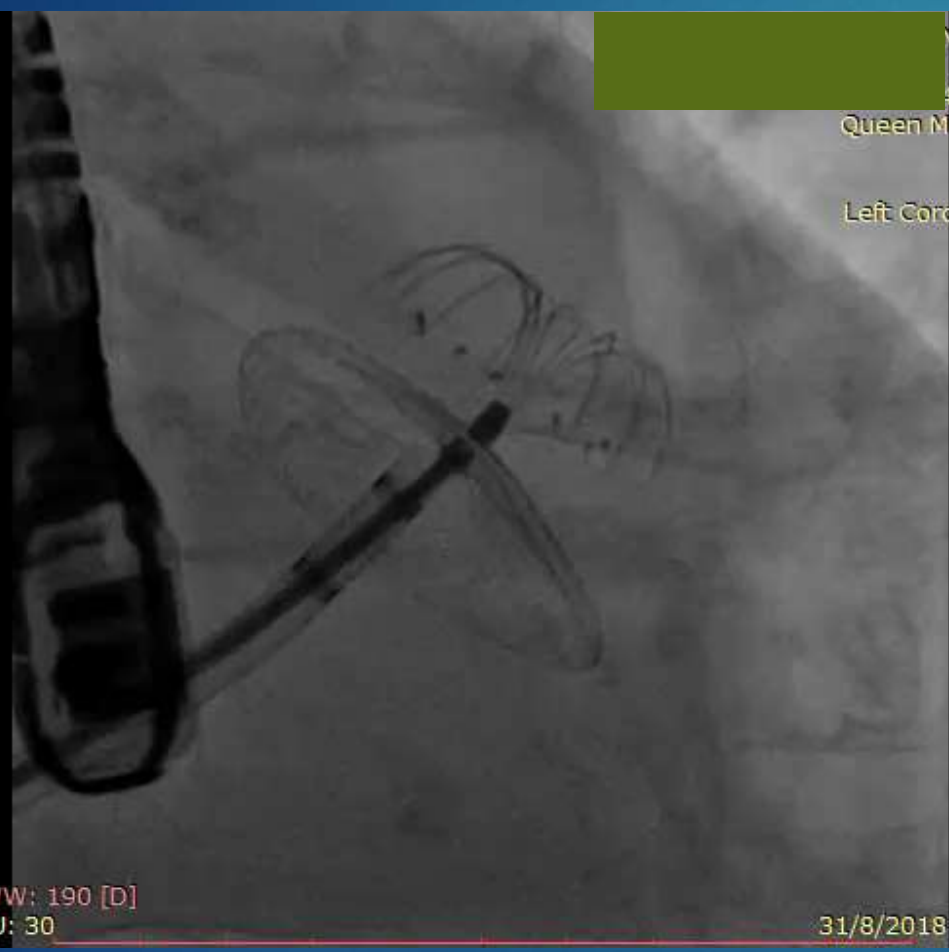
Im: 1/25  
Se: 10

Queen Mary Hospital  
1141-2018  
XA  
Left Coronary 15 fps



Im: 1/26  
Se: 9

NG F  
A:  
4/12  
Queen Mary  
11  
Left Corona



WL: 129 WW: 190 [D]  
LAO: 6 CAU: 30

FR 50HZ  
14cm  
ZD  
61%  
C 50  
P Off  
HGen



WL: 129 WW: 190 [D]  
LAO: 6 CAU: 30

31/8/2018 4:18:21 PM

PAT T: 37.0C  
TEE T: 39.4C

JPEB  
88 bpm



Im: 207/293  
Se: 13



Queen Mary Hospital  
1141-2018  
XA  
Fluoroscopy

PHILIPS

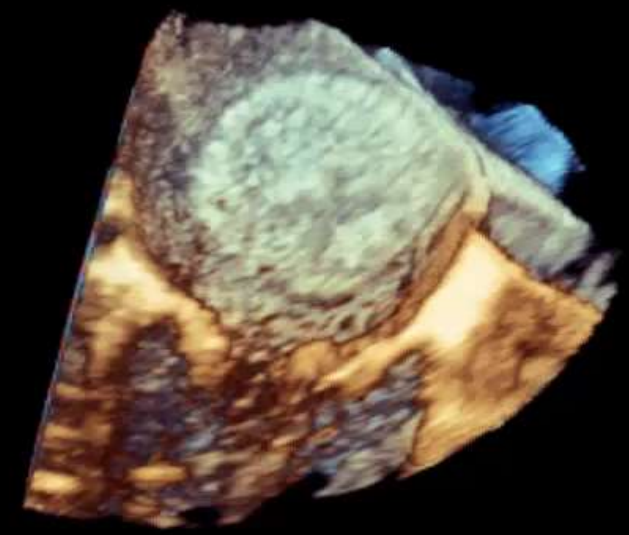
31/08/2018 16:25:50 TIS0.4 MI 0.7  
X7-2t/Adult

FR 6Hz  
8.5cm  
3D  
3D 47%  
3D 40dB

3D Beats 1



M4



JPEG

48 bpm

WL: 115 WW: 213 [D]  
RAO: 30 CRA: 20

31/8/2018 4:21:23 PM

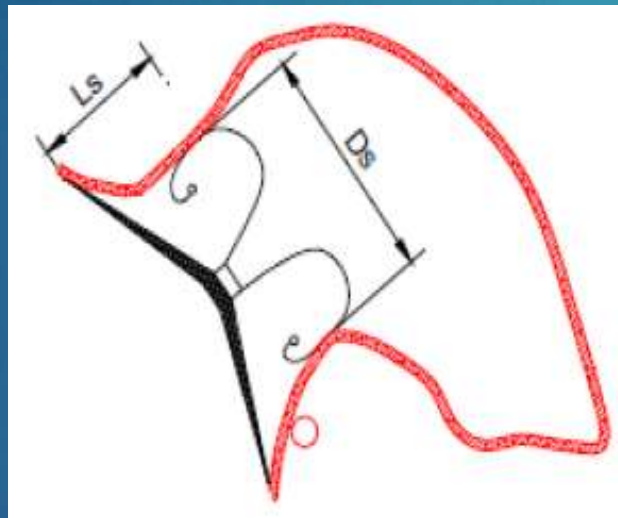
PAT T: 37.0C  
TEE T: 39.5C



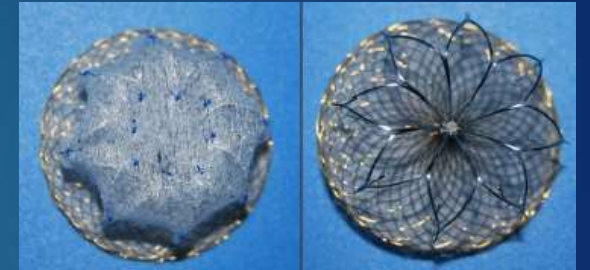
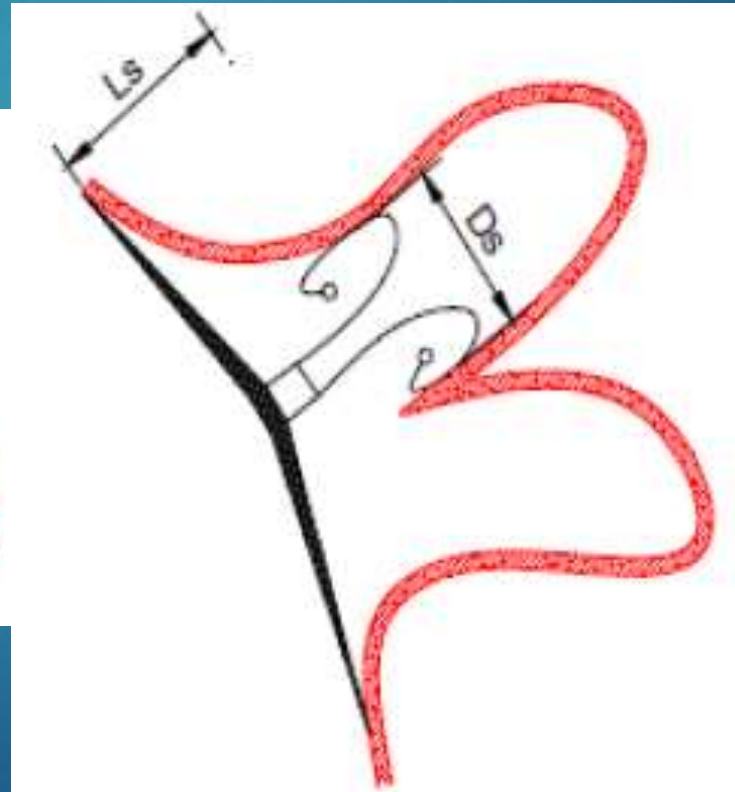
## ► Case Illustration 2

# Special LAA Morphology

- Small LAA
- LAA with multiple lobes and restrictive septum



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



Size: 16-26mm  
Cover 12mm larger



Im: 1/72

Se: 8

Queen Mary Hospital

0536-2019

XA

Left Coronary 15 fps

WL: 129 WW: 190 [D]

RAO: 30 CAU: 20



Im: 1/1  
Se: 8

Queen Mary Hospital  
0536-2019  
XA  
Left Coronary 15 fps



WL: 512 WW: 1024 [D]

CF: 0.1305 mm/pix

12/4/2019 12:17:41 PM

FR 14Hz  
7.9cm

3D Beats 1

M4

3D  
3D 47%  
3D 40dB

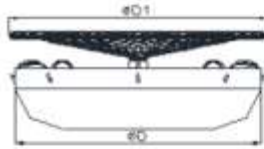


JPEG

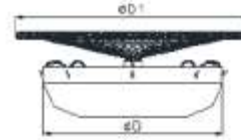
PAT T: 37.0C  
TEE T: 38.7C

70 bpm

# 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
LT-LAA-1824	18	24	10F-900
LT-LAA-2026	20	26	9F-900
LT-LAA-2228	22	28	10F-900
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	

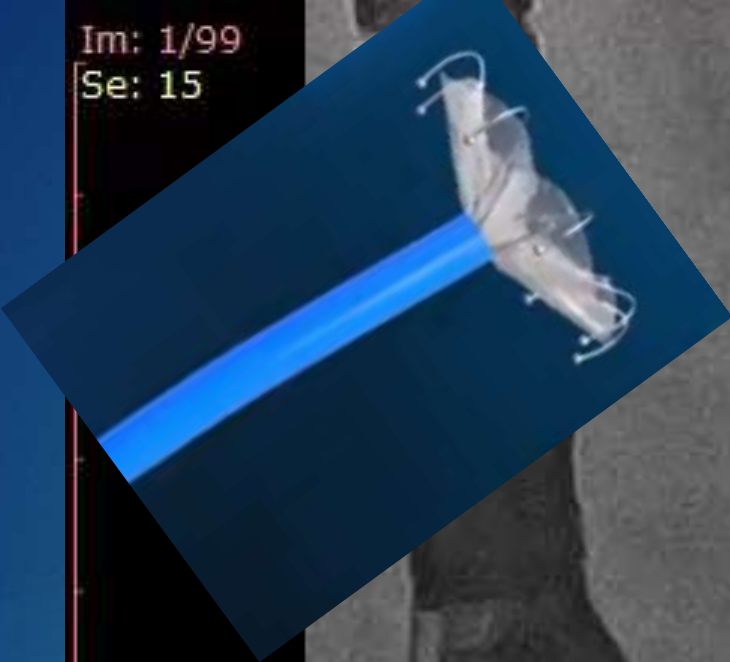


Cat.	Diameter of Umbrella(mm)	Diameter of Cover(mm)	Delivery system
LT-LAA-1630	16	30	9F-900 10F-900
LT-LAA-1832	18	32	
LT-LAA-2032	20	32	
LT-LAA-2234	22	34	10F-900
LT-LAA-2436	24	36	
LT-LAA-2638	26	38	



Im: 1/99  
Se: 15

Queen Mary Hospital  
0536-2019  
XA  
Fluoroscopy



WL: 115 WW: 213 [D]  
RAO: 30 CAU: 20

12/4/2019 12:49:15 PM



Queen Mary Hospital  
0536-2019  
XA  
Fluoroscopy

WL: 115 WW: 213 [D]  
RAO: 32 CAU: 17

PHILIPS 12/04/2019 12:54:22 TIS0.2 MI 0.5  
X7-2t/Adult

FR 18Hz 10cm 3D Beats 1 M4

3D 47% 3D 40dB

JPEG 58 bpm

PAT T: 37.0C  
TEE T: 39.5C

The complex block contains a Philips ultrasound interface. At the top, it shows the brand name 'PHILIPS' and patient information including date '12/04/2019', time '12:54:22', and technical parameters 'TIS0.2 MI 0.5 X7-2t/Adult'. Below this, it displays 'FR 18Hz 10cm', '3D Beats 1', and 'M4'. A 3D icon and a gauge showing '3D 47%' and '3D 40dB' are visible. The main part of the block is a 3D echocardiogram image of a heart cross-section with a color Doppler overlay. At the bottom right, it shows 'JPEG' and '58 bpm'. At the bottom left, it shows 'PAT T: 37.0C' and 'TEE T: 39.5C'.

Im: 1/17  
Se: 19

Queen Mary Hospital  
0536-2019  
XA  
Left Coronary 15 fps



LAMBRE #22/34mm

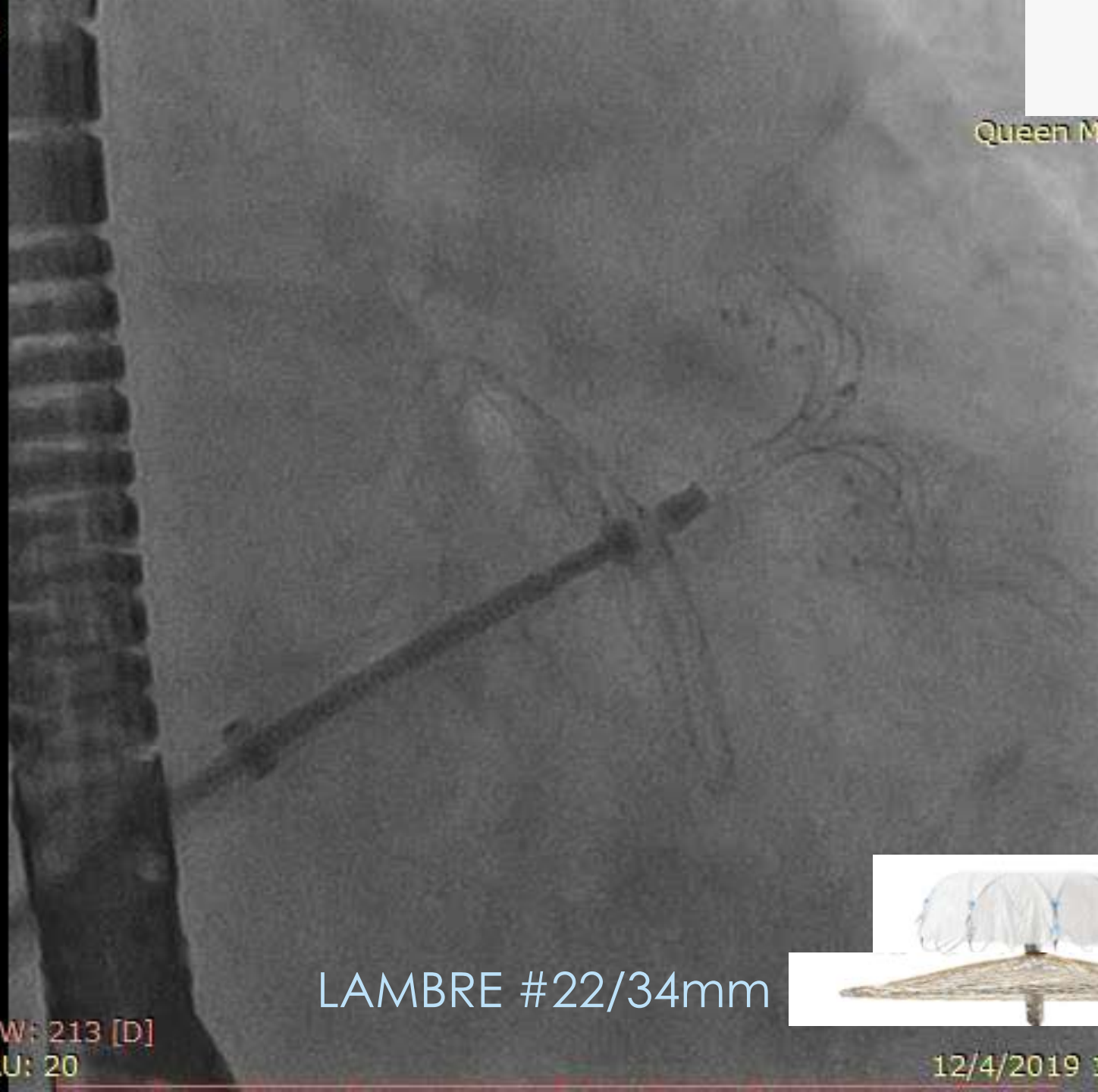


WL: 129 WW: 190 [D]  
RAO: 30 CAU: 20

12/4/2019 12:55:24 PM

Im: 90/248  
Se: 22

Queen Mary Hospital  
0536-2019  
XA  
Fluoroscopy



LAMBRE #22/34mm



WL: 115 WW: 213 [D]  
RAO: 30 CAU: 20

12/4/2019 12:56:51 PM



Im: 1/48  
Se: 26

Queen Mary Hospital  
0536-2019  
XA  
Left Coronary 15 fps

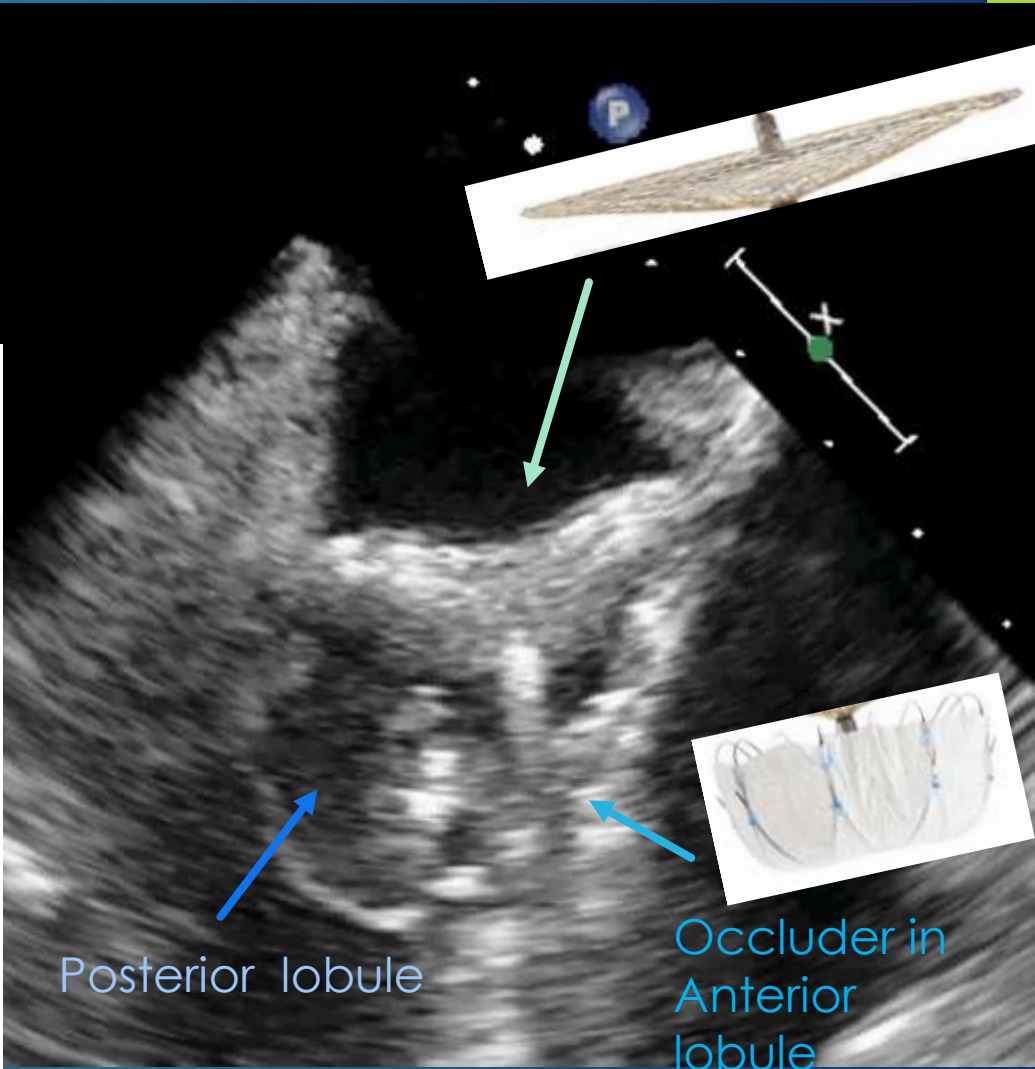
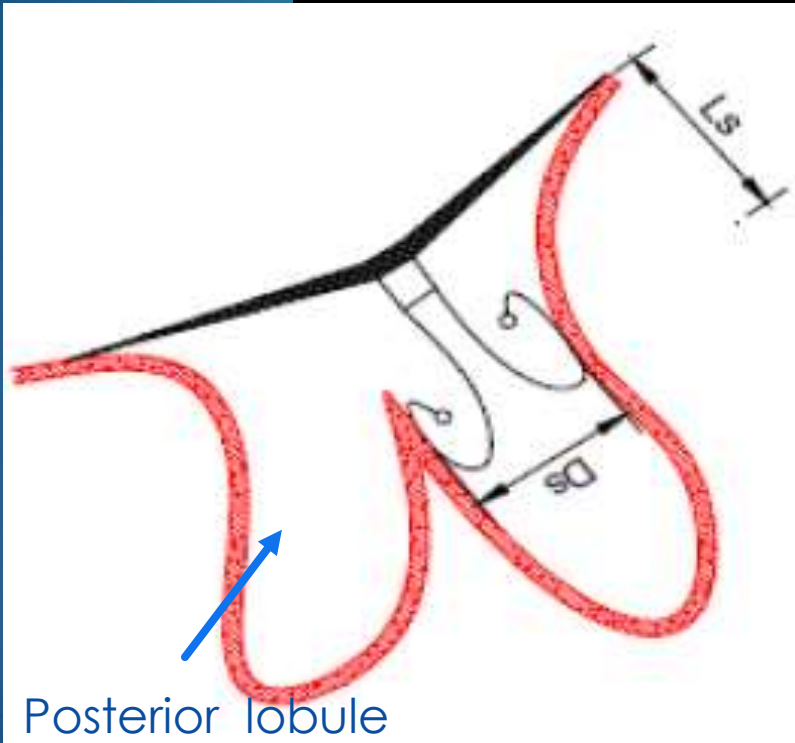


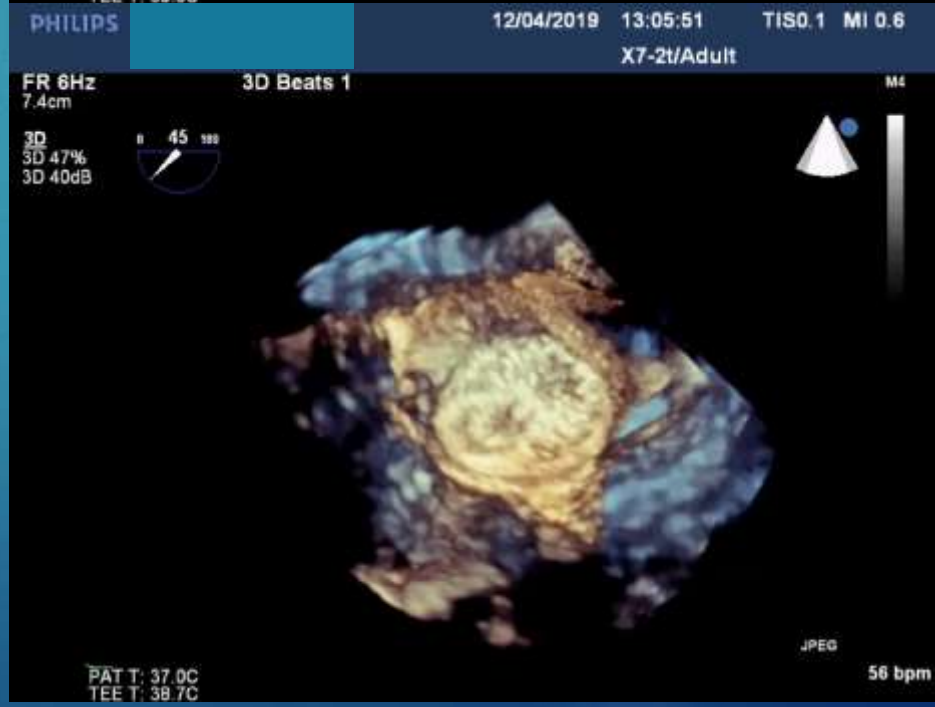
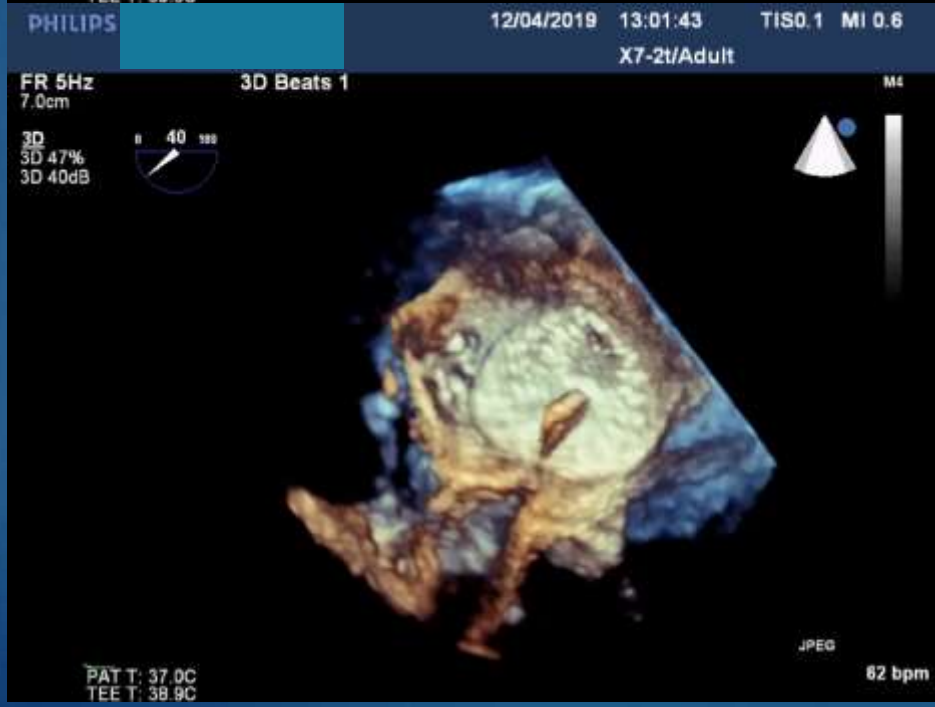
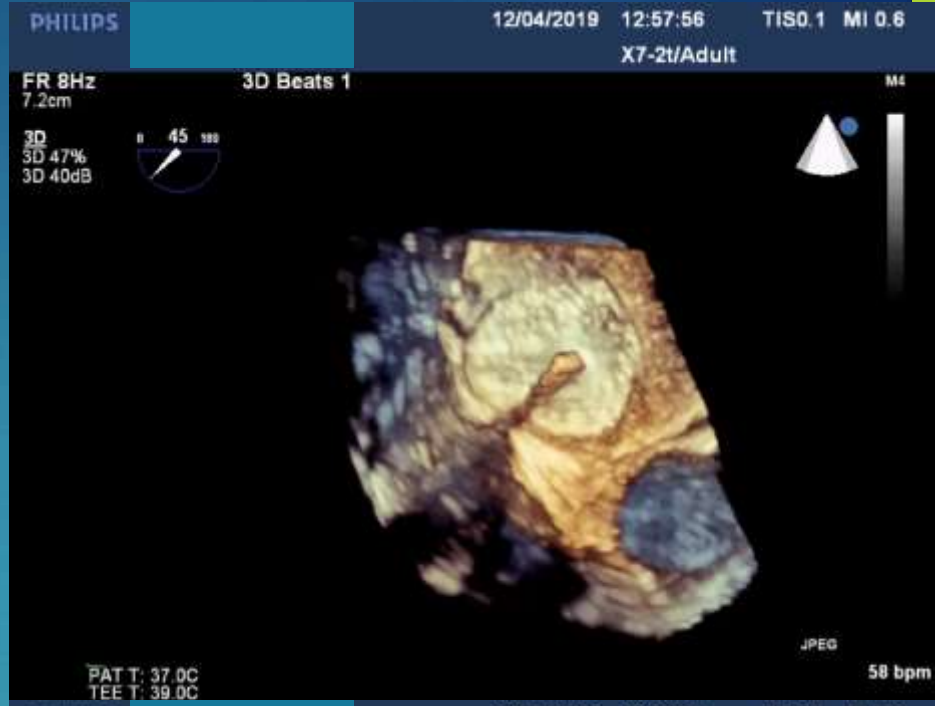
LAMBRE #22/34mm



WL: 129 WW: 190 [D]  
RAO: 30 CAU: 20

12/4/2019 1:00:15 PM

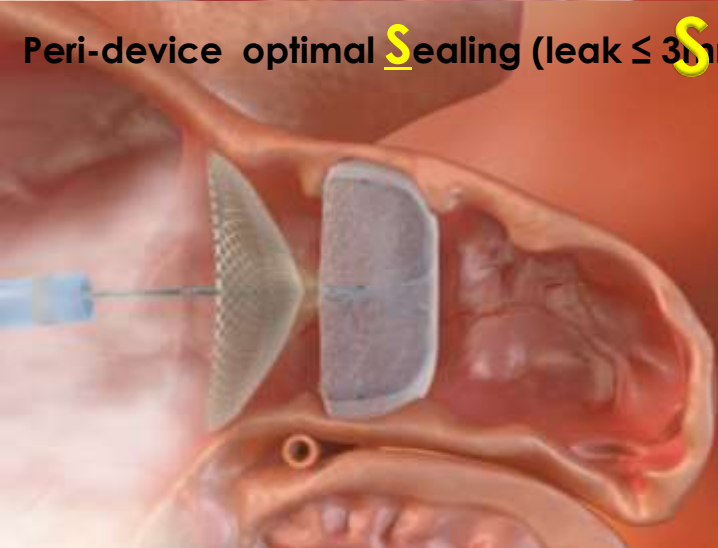
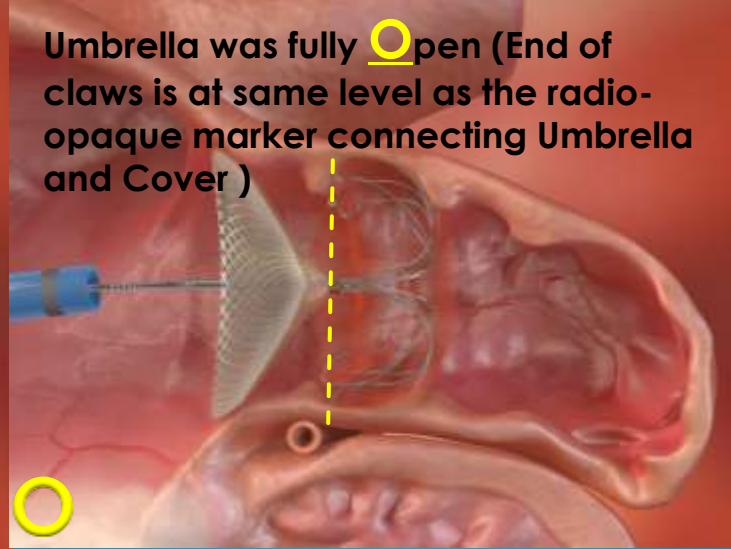
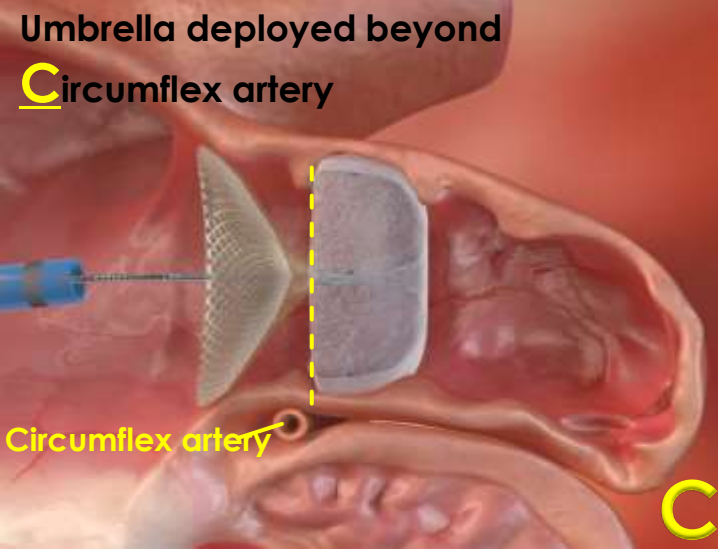






# Clinical Applications

Device deployment principles



Before releasing the cable,  
you must confirm the COST  
principle



# China

## **LAmbre Study in China [1]**

- ▶ 153 Patients, 12 Centers.
- ▶ Prospective, multicenter, open label, nonrandomized pilot trial
- ▶ Endpoint: safety, feasibility and efficacy of deploying LAmbre LAA occlusion device.
- ▶ Conclusion: LAA Closure with the LAmbre device shows encouraging results for stroke prevention in patients with NVAF.

[1] JACC: CARDIOVASCULAR INTERVENTIONS VOL. 10, NO.21,2017.

# Europe

## **LAmbre Study in Europe [1]**

- ▶ 60 Patients, 2 Centers in Germany.
- ▶ First European Experience with LAmBre.
- ▶ Conclusion: Although minimizing procedure-related complications remains challenging, LAAO with the LAmBre showed high device success and good mid-term performance regarding prevention of stroke and bleeding.

# Post-Market Clinical Follow-up

## **Lifetech LAmbre™ Left Atrial Appendage Closure System**

### **Post-Market Clinical Follow-up(LISA Study)**

Study Design: Multi-center, single-arm, prospective, post-market study of LAmbre™ LAA Closure System

Principal Investigator: Prof.Horst Sievert, Hospital: Frankfurt CVC

Primary Objective: To evaluate immediate and long term procedural success of Lifetech LAmbre™ Occluders in patients.

Number of Subjects: 500 Patients

# Post-Market Clinical Follow-up

Total 26 centers;

13 centers from Germany;

PI	Site name	Country /Region
PD Dr. med. Kars Neven	Alfried Krupp Krankenhaus (Enrolment Completed)	Germany
PD Dr. med. Boris Schmidt	Cardioangiologisches Centrum Bethanien	Germany
Prof. Dr. med. Carsten Skurk	Charité Campus Benjamin Franklin	Germany
Dr. med. Alexander Sedaghat	Universitätsklinikum Bonn	Germany
PD Dr. med. Marcus Sandri	Herzzentrum Leipzig	Germany
Prof. Dr. med. Horst Sievert	CardioVasculäres Centrum	Germany
Prof. Dr. med. Thorsten Lewalter	Peter-Osypka-Herzzentrum	Germany
Dr. med. Ralph Stephan von Bardeleben	University Medical Center of Johannes Gutenberg-University Mainz	Germany
Dr. med. Anke Langbein	Praxisklinik Herz und Gefäße	Germany
Prof. Dr. med. Stefan G. Spitzer		
PD Dr. med. Sven Möbius-Winkler	Universitätsklinikum Jena	Germany
Dr. med. Norbert Klein	Klinikum St. Georg	Germany
Dr. med. Steffen Schnupp	Klinikum Coburg GmbH	Germany
PD Dr. Leif-Hendrik Boldt	Charité Campus Virchow Klinikum	Germany



# Post-Market Clinical Follow-up

4 centers from Italy; 3 centers from Spain;  
Single center from Poland, Sweden, Hong Kong, Denmark, Ireland & Thailand.

PI	Site name	Country /Region
Prof. Achille Gaspardone	Ospedale S. Eugenio-ASL Roma 2	Italy
Dr. Jacopo Andrea Oreglia	ASST Grande Ospedale Metropolitano Niguarda	Italy
Prof. Claudio Tondo	Centro Cardiologico Fondazione Monzino	Italy
Clinica Mediterranea	Dr. Carlo Briguori	Italy
Prof. Ignacio Cruz Gonzalez	University Hospital Salamanca	Spain
Dr. Xavier Freixa Rofastes	Hospital Clínic de Barcelona	Spain
Dr. Beatriz Vaquerizo	FundacióInstitut Hospital del Mar d'Investigacions Mèdiques	Spain
Prof. Jan Z. Peruga	Bieganski Hospital	Poland
Prof. Dr. Jacob Odenstedt	Sahlgrenska University Hospital	Sweden
Dr. Simon Lam	Queen Marry Hospital	Hong Kong China
Prof. Dr. Jens Erik Nielsen Kudsk	Aarhus University Hospital	Denmark
Prof. Kevin Walsh	Mater Misericordiae University Hospital	Ireland
Ramathibodi Hospital	Dr. Mann Chandavimol	Thailand

# Conclusion

- Device innovations and selections
- **2-Component Devices**
  - AMULET
  - LAmbre
- Precautions and avoidance of potential complications
- **Results and outcome optimization**

