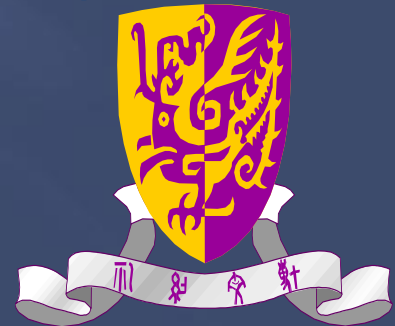


# Lambre LAA Occluder Updates

**5<sup>th</sup> APCASH  
Hong Kong  
10th October, 2014**

**Yat-yin LAM MBBS MRCP FHKCP FHKAM FESC FRCP FACC MD**

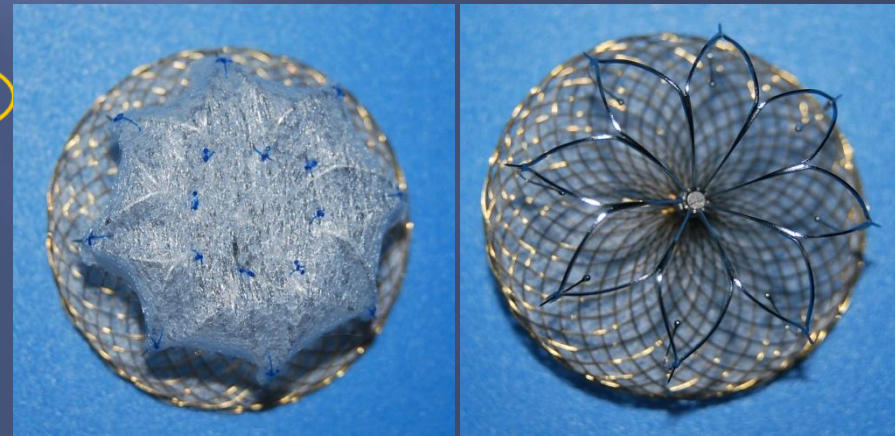
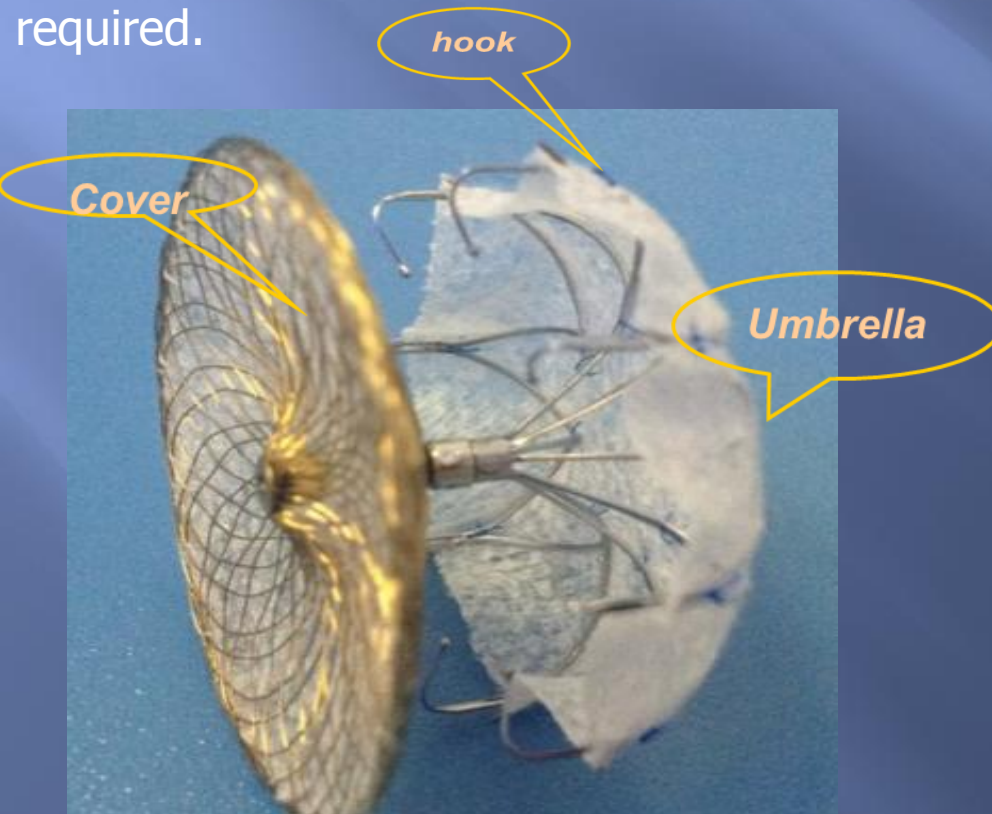
Associate Professor, Prince of Wales Hospital, The Chinese University of Hong Kong (CUHK)  
President, Hong Kong Society of Congenital and Structural Heart Disease (HKCASH)



# Lifetech LAA occluder - LAmbre™

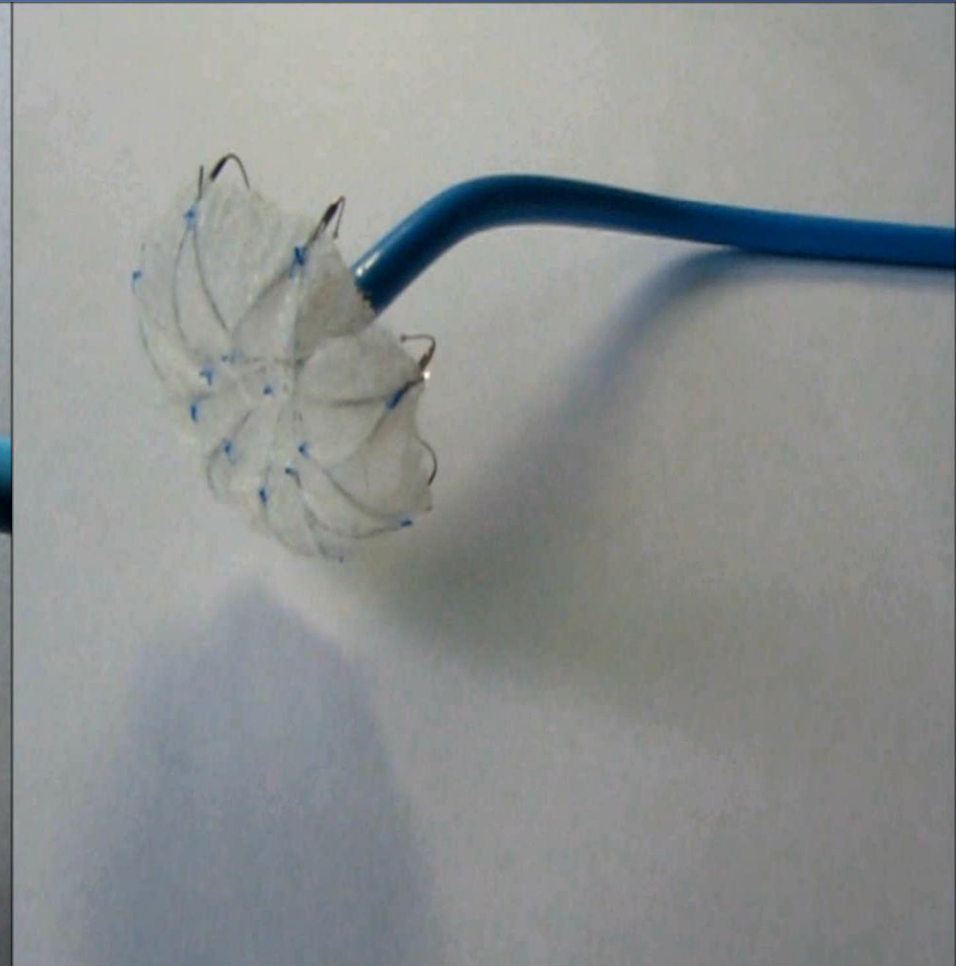
## Characteristics

1. Two parts : LA Cover and Umbrella. **"An Umbrella in LA Appendage "**
2. **Double-membrane design**: A distal membrane to seal the appendage if that in the cover fail to do so.
3. **TiN-coated LA cover with recessed hub** to promote faster endothelialization and to reduce delayed thrombus formation.
4. **Specially-designed umbrella (8 frames+ PET membrane+ 8 hooks)** for multiple recapture and repositioning; only smaller sheaths (8-10Fr, Sizes 16-36mm) required.



# Deployment

# Recapture

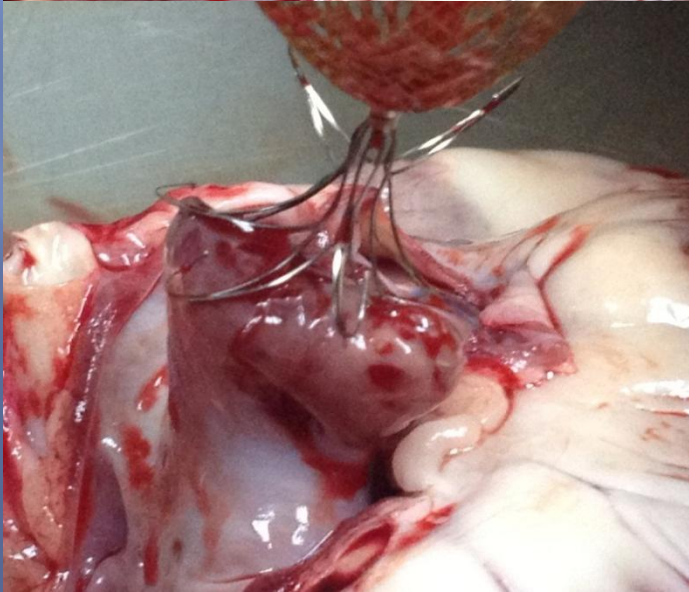
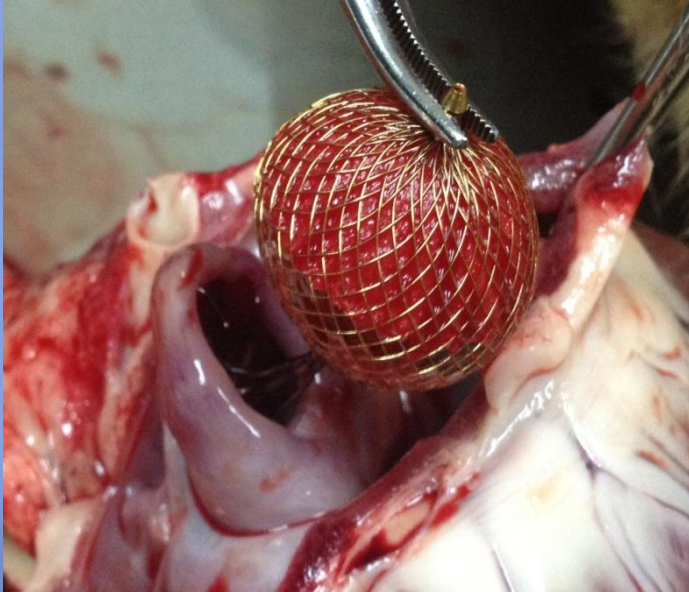


# Anchoring Mechanisms



## 3 Anchoring Mechanisms:

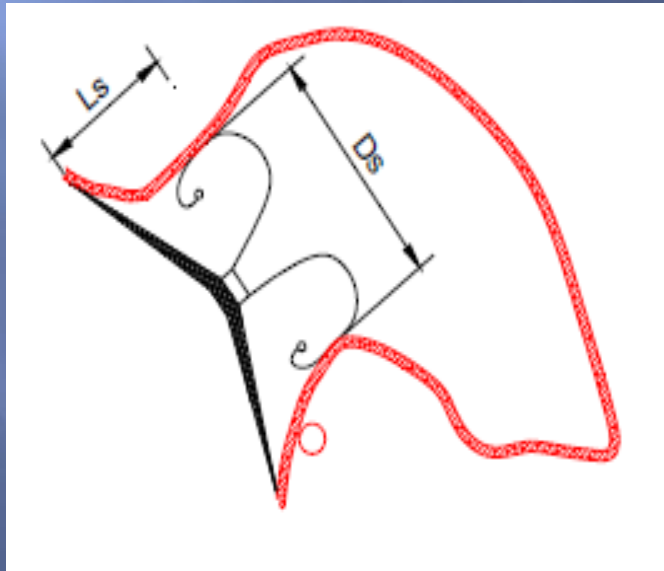
- 8 small hooks
- Stenting effect of the over-sized umbrella
- 8 individual frames (trapped in trabeculations)



# Two Specifications

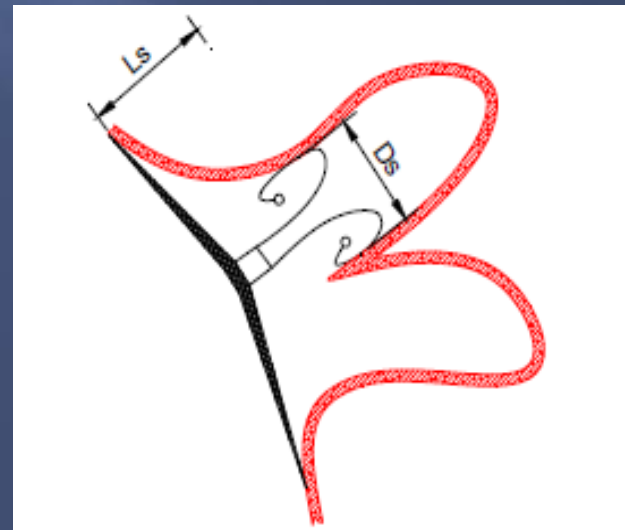
## Standard

- ▣ 16-36mm
- ▣ Cover 4-6mm larger

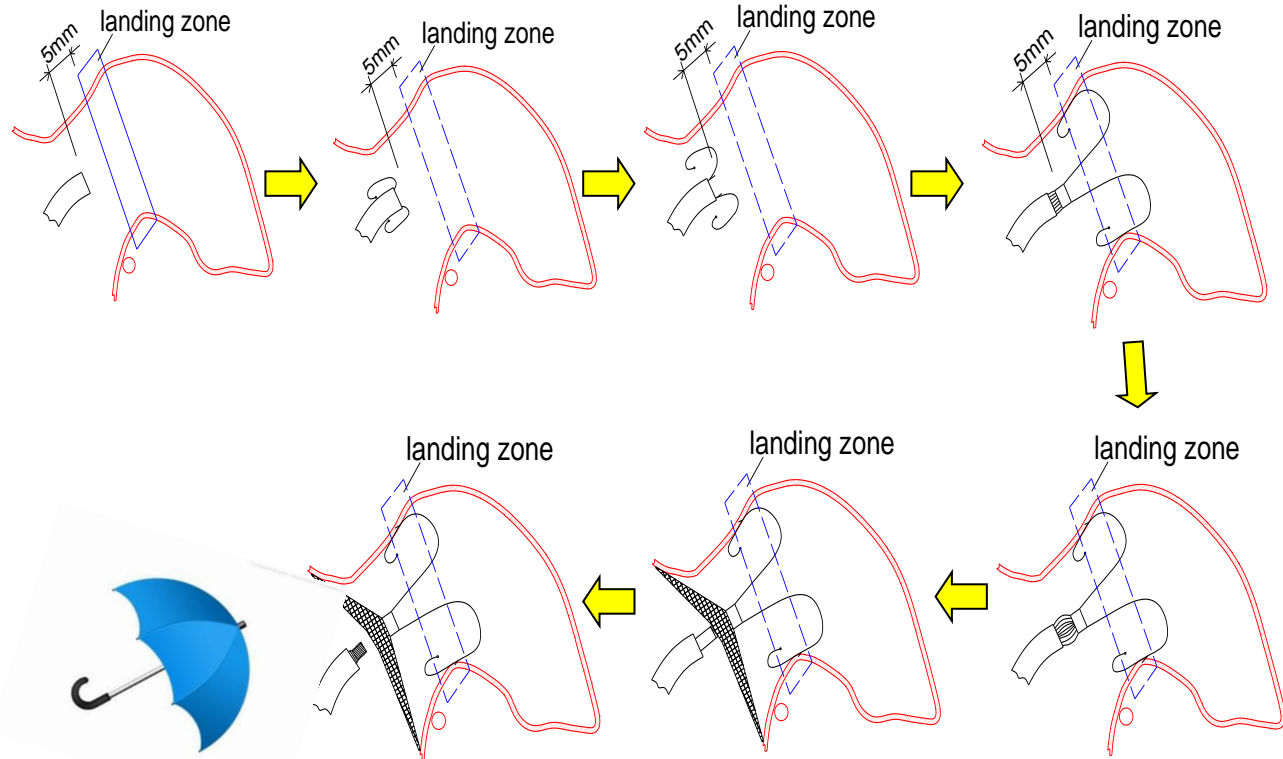
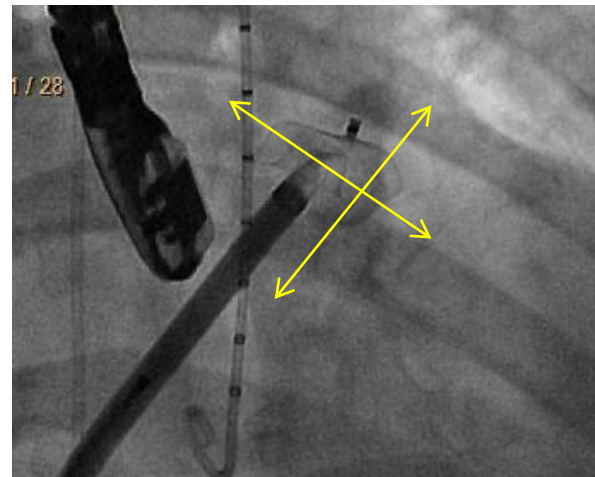


## Special

- ▣ 16-26mm
- ▣ Cover 12-14mm larger
- ▣ Suitable for:
  - multiple lobes with restrictive septum
  - Small LAA with large opening



# Procedural Steps



- > Opening up the umbrella at proximal LAA (active roll-in of stabilizing hooks)
- > Distal positioning of delivery catheter is not required!
- > Less demanding on catheter alignment in perpendicular to ostial axis!!

# Comparisons with Current LAA occluders

**WATCHMAN**

**ACP**

**LAmbre**

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## Device Design

**Leak** More likely

Less likely

Less likely

**Dependence on LAA depth** YES

No

No

**Delivery Sheath** 14 Fr

9-13 Fr (13)

8-10 (9)

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## Procedural control

**Deep seating of delivery catheter** Required

Not required

Not required

**Backward bounce of the device** No

Yes

No

**Recapture and Repositioning** Limited

Limited

Full

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# Clinical Studies Updates Sept 2014

- ▣ 192 human implants were then performed successfully (184/184 attempts, 100% implant success)
  - 132 : Asian Registry – China, Hong Kong, Vietnam, Indonesia (Oct 2012 – Oct 2014)
  - 60: 2 German Centers for CE study (Nov 2013 – June 2014)



# Transcatheter Left Atrial Appendage Closure with Lifetech LAmbre Device: Early Asian Experience

Yat-Yin Lam<sup>1</sup>, Yan Yao<sup>2</sup>, Congxin Huang<sup>3</sup>, Nguyen Lan Hieu<sup>4</sup>, Muhammad Munawar<sup>5</sup>  
Yawei Xu<sup>6</sup>

1. Prince of Wales Hospital, The Chinese University of Hong Kong
2. Fuwai Hospital, Beijing, China
3. Renmin Hospital of Wuhan University, China
4. Hanoi Heart Hospital, Vietnam
5. Binawaluya Hospital, Indonesia
6. Shanghai Tenth People's Hospital of Cardiology, China

# Lambre FIM Asian Registry (n=66)

- ▣ Oct 2012 – June 2014
- ▣ 6 Asian Centers: Hanoi (n=2), Jakarta (n=18), Beijing (n=4), Wuhan (n=7), Hong Kong (n=3), Shanghai (n=32)
- ▣ Inclusion: Stable NVAF patients with CHA2DS2-VASc $\geq$ 2
- ▣ Exclusion: LAA thrombus, NO anatomical exclusion criteria
- ▣ Feasibility: Stable device placement without significant leak (>3mm peri-device leak)
- ▣ Safety: A composite of CV death, device embolization, stroke, systemic embolism, MI, pericardial effusion/cardiac tamponade, major bleeding requiring intervention/transfusion, & need for CV surgery 7 days within the procedure

# Lambre FIM Asian Registry (n=66) – Acute Procedural Outcomes

- ▣ 66 NVAF patients; Aged  $67 \pm 10$ ; 50% Male (n=33)
- ▣ CHA2DS2-VASc:  $3.8 \pm 1.4$ ; HAS-BLED:  $2.4 \pm 1.2$
- ▣ Procedure: General anesthesia/Deep sedation (n=61), Local anesthesia (n=6); Fluoroscopic +/- TEE guidance
- ▣ Procedural time (min):  $63 \pm 21$ ; Fluoro. time(min):  $12 \pm 4$
- ▣ Landing zone diameter(mm):  $22.2 \pm 4.8$ ; Device size (mm):  $26.7 \pm 4.5$
- ▣ Standard device (n=62), special device (n=4)
  
- ▣ Feasibility: Successful device implantation 100% ; Significant Peri-device leakage (color-Doppler width>3mm): 1 (4mm leak)
- ▣ Safety (7-day events): 2 air-embolism, 1 mild pericardial effusion, no stroke or device embolization, no transfusion needed

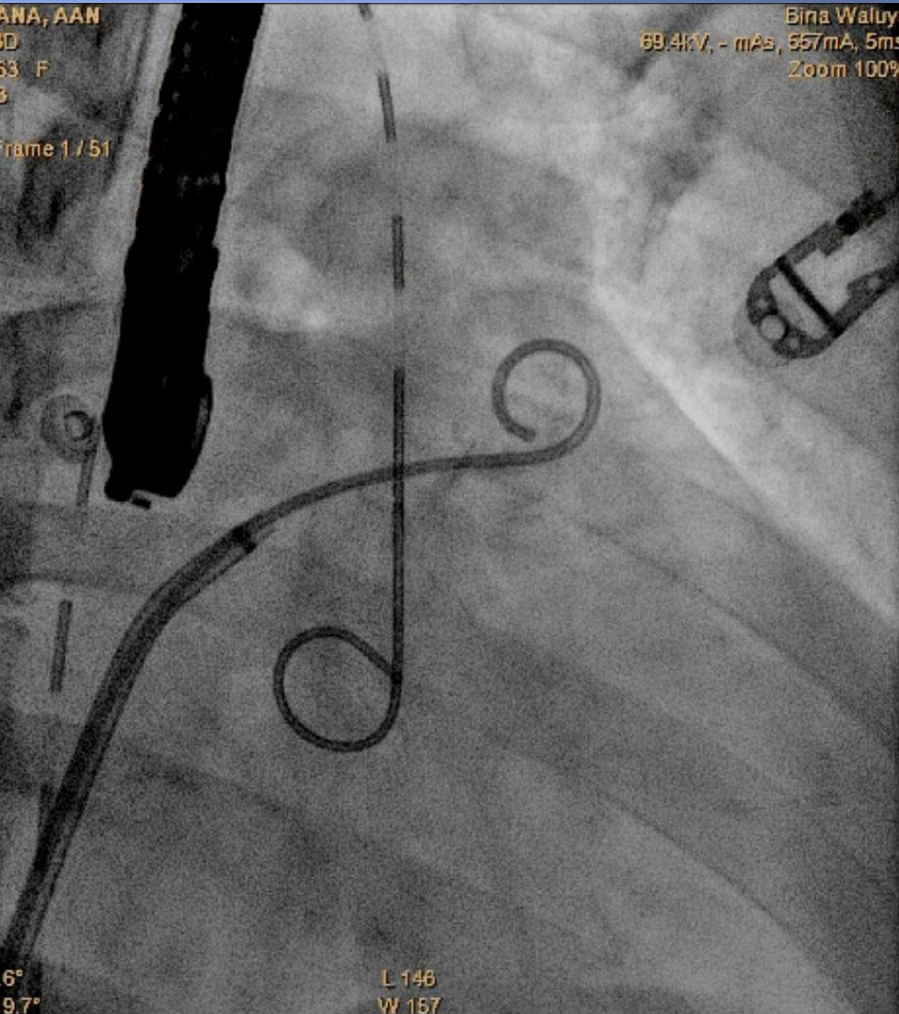
# Severe procedural-related complications compared with other 2 devices

	PROTECT-AF	ACP Retrospective European Registry	Lambre Global Registry
No of patients (time of follow-up)	463 (7 days within procedure)	143 (<24 hour or upon discharge)	#192 (7 days within procedure)
Implantation success	401/463 (91%)	132/137 (96%), not attempted in 6	192/192 (100%)
Serious pericardial effusion	22 (4.8%)	5 (3.5%)	*2 (1.0%)
Procedural stroke	5 (1.1%)	3 (2.1%)	1 (0.5%)
Device embolization	3 (0.6%)	2 (1.4%)	0 (0%)

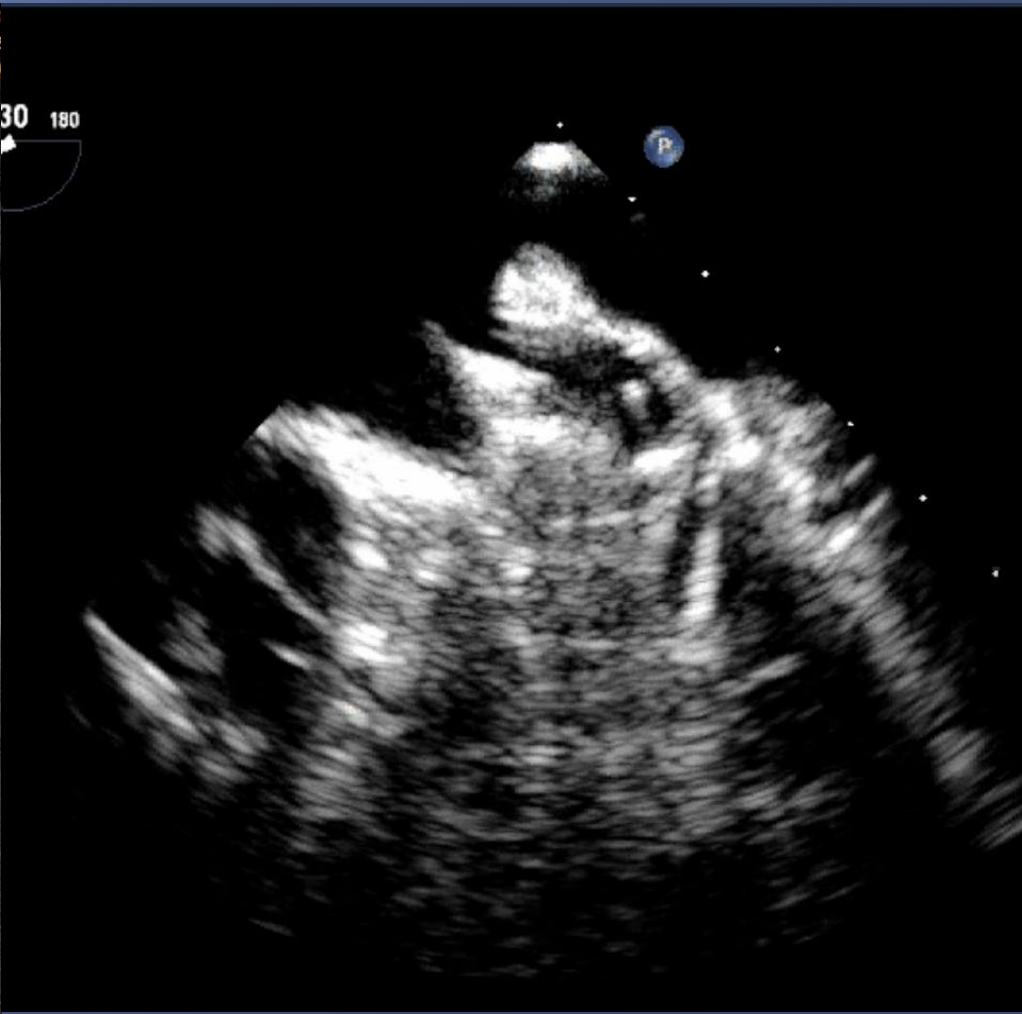
#the only exclusion criteria was the presence of LAA thrombus, no other anatomical exclusion criteria (i.e. patients with small, large or shallow LAA all included)

\*1 due to stiff guidewire perforation of LAA during procedure, another due to delayed effusion 7days after implantation

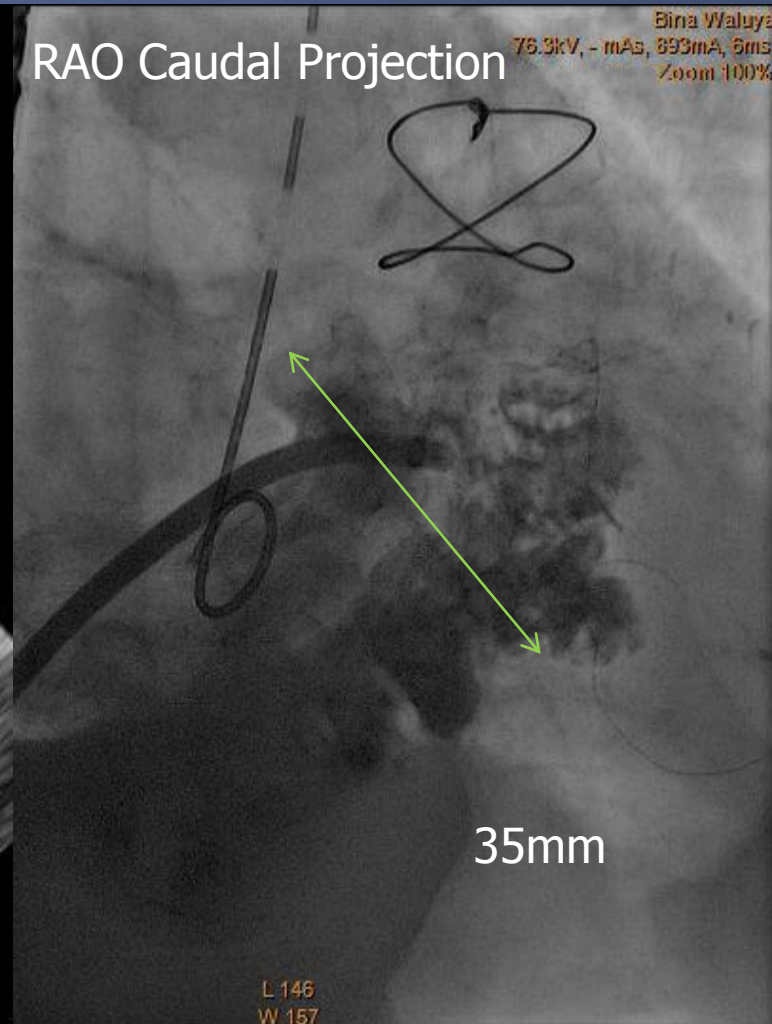
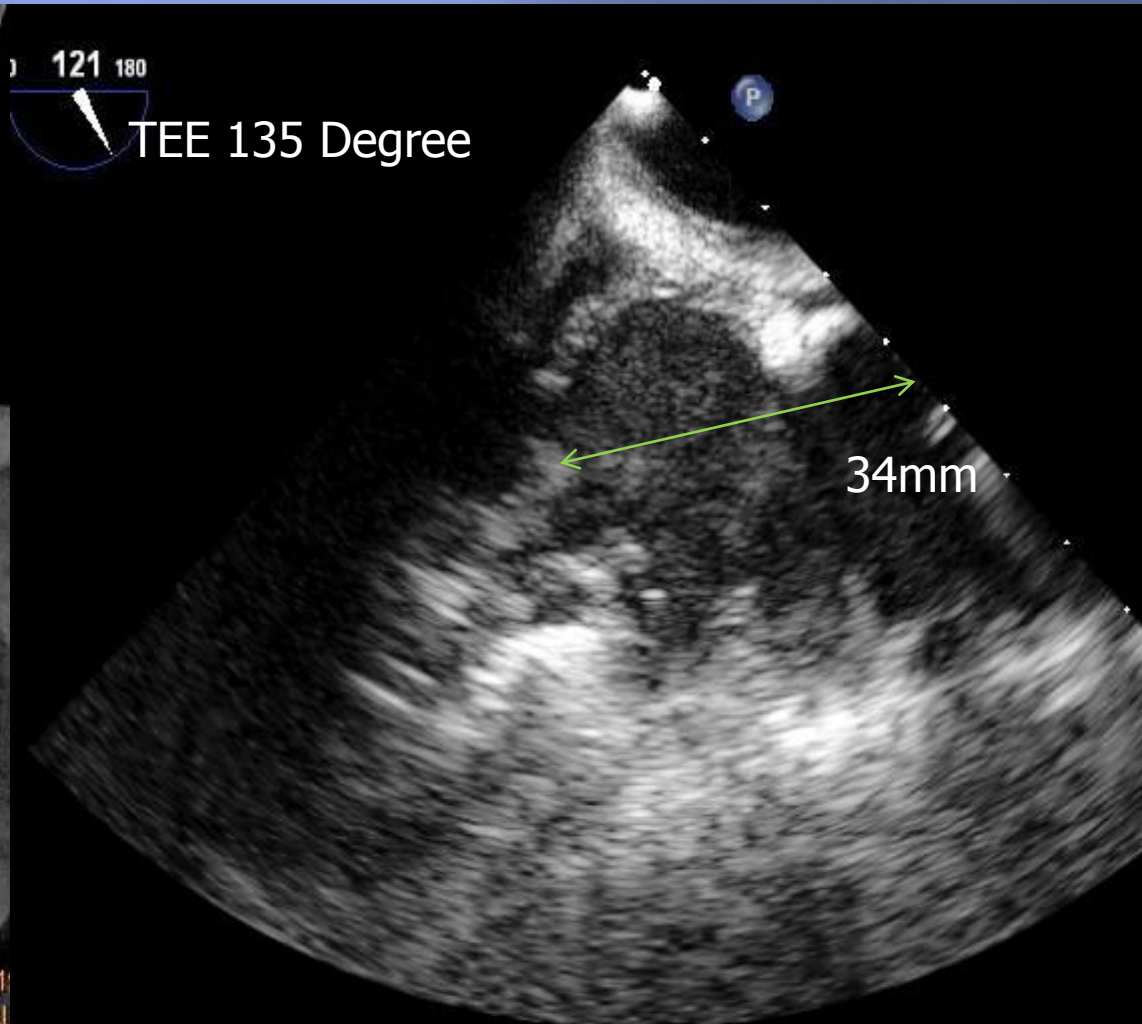
# Case 1 - Routine Case



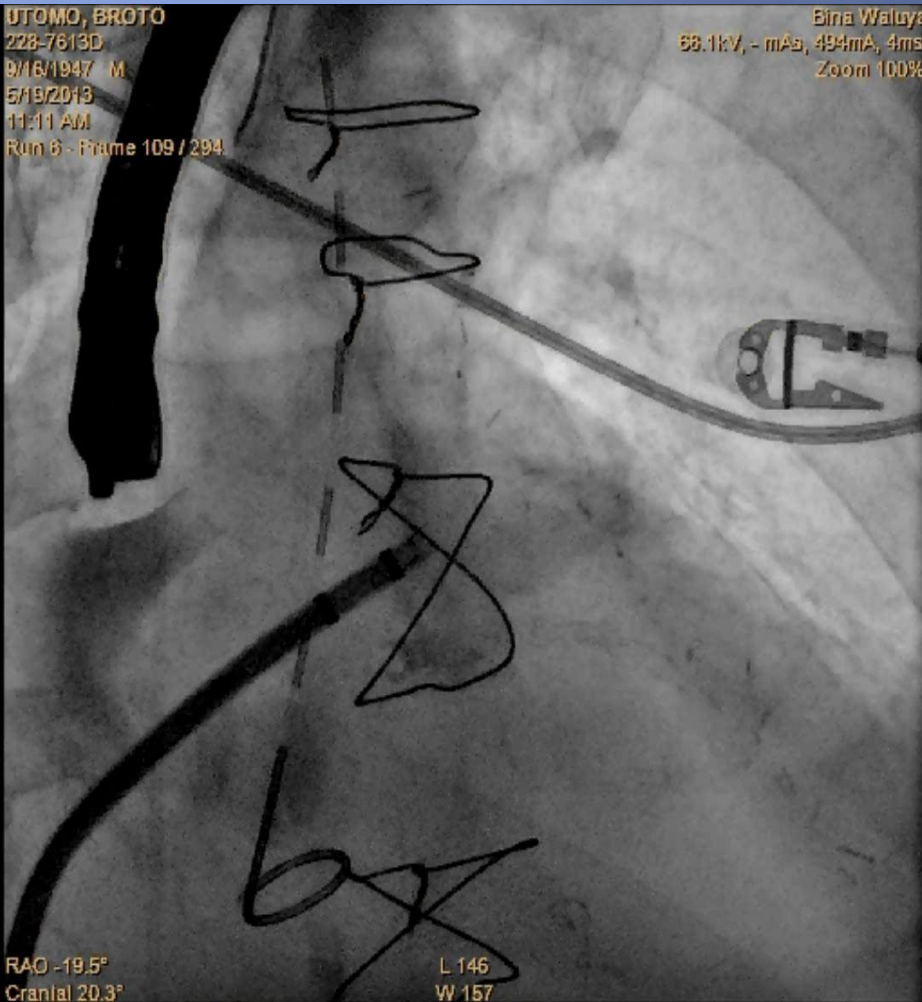
30 180



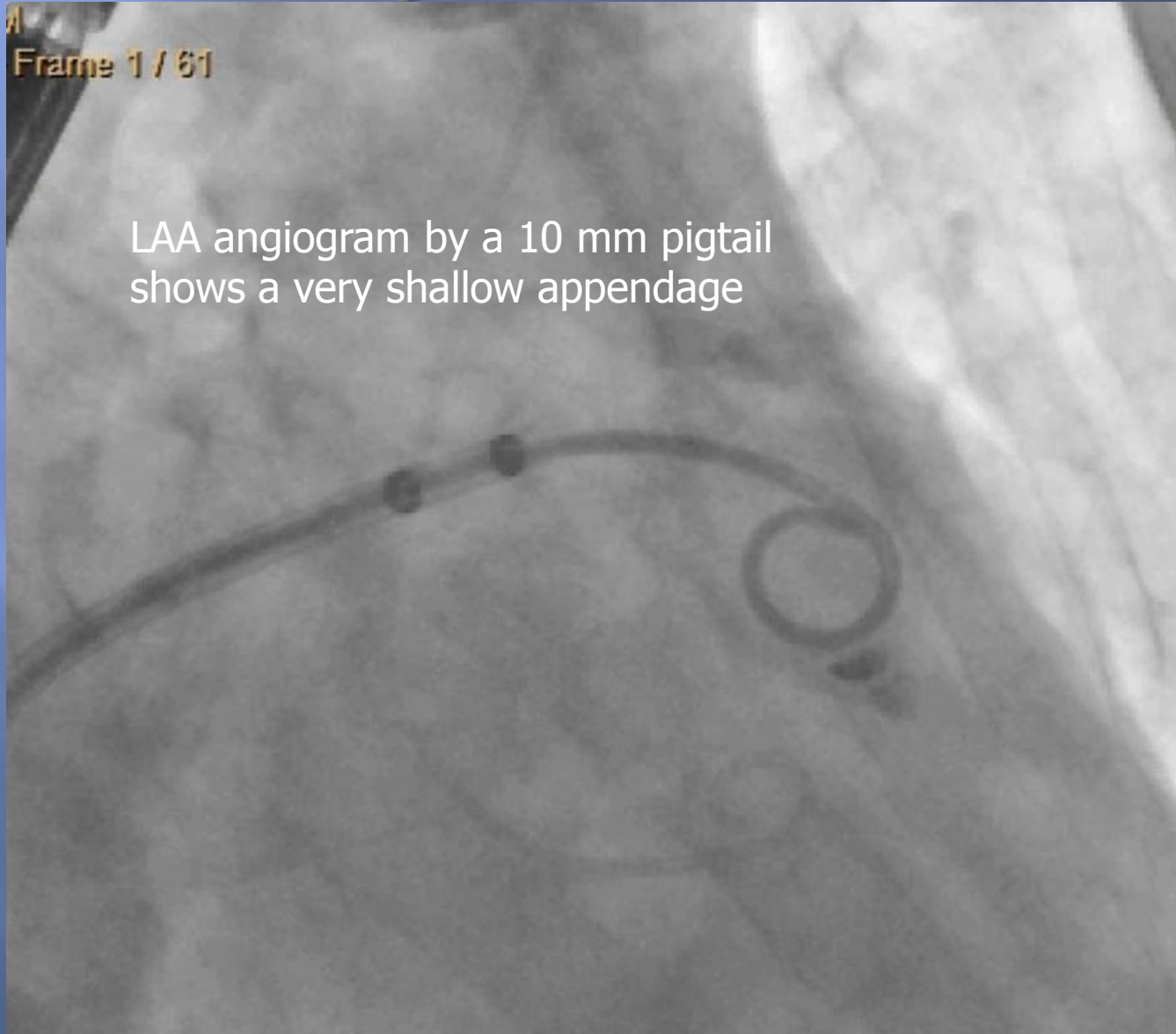
# Case 2- Large Appendage



# Large Appendage – 36mm device, 10 Fr sheath



# Case 3 Shallow Appendage (LAA depth < 10mm)

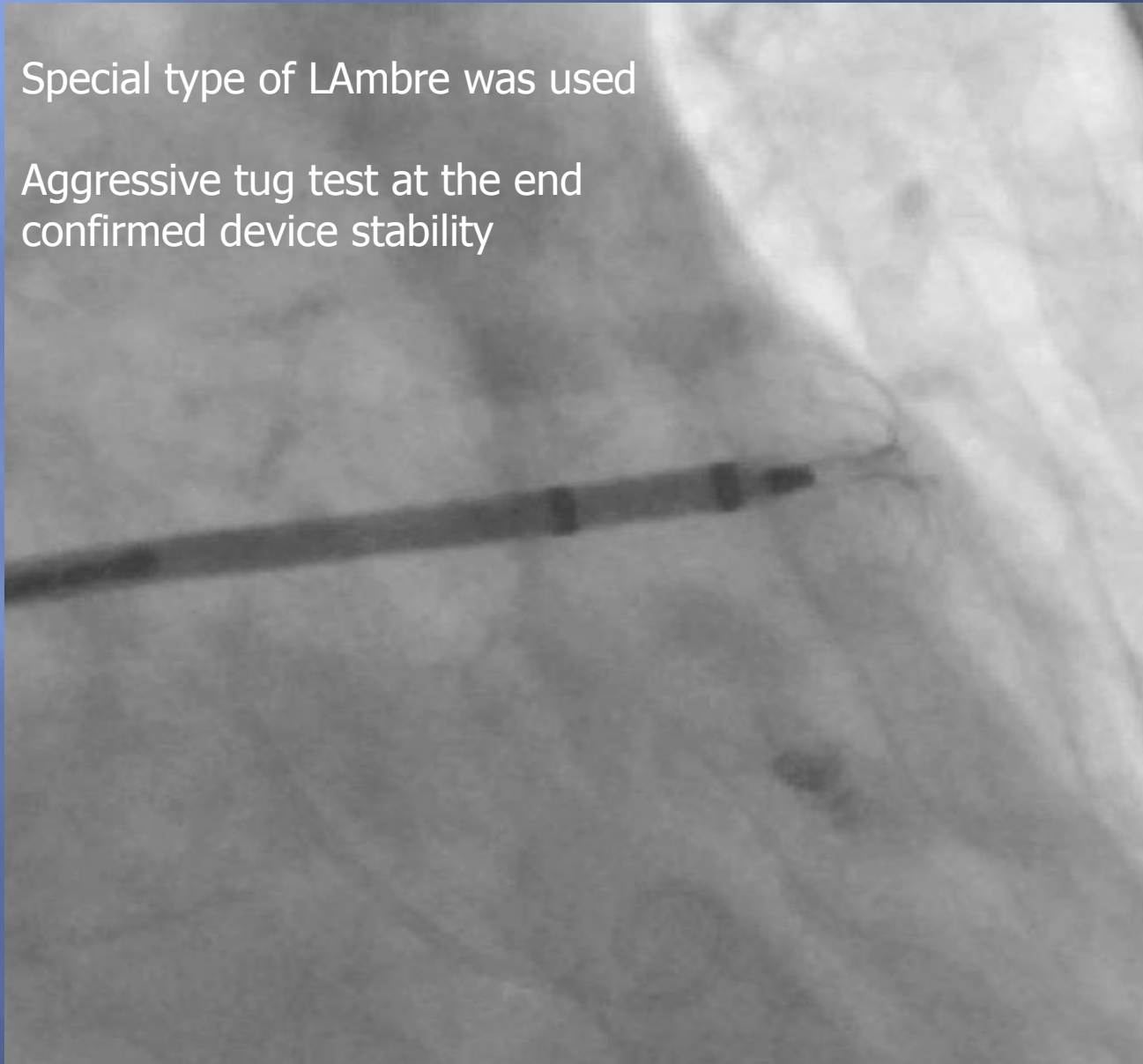




# Shallow Appendage – closed with LАmbre 16/30 device!!

Special type of LАmbre was used

Aggressive tug test at the end  
confirmed device stability



# Conclusions

- ▣ Our preliminary human experience in Asia suggested LAA occlusion with LAmbre device is feasible in various LAA anatomies with no serious peri-procedural events.
- ▣ Main advantages of this device include small delivery system, ease of use and the ability to be fully retrievable and repositionable during implantation.
- ▣ Human trials with this novel device are underway in Asia/Europe to evaluate its long-term safety and efficacy.

# Thank You

