LAAO Challenging cases – Advanced Techniques and New Devices

Philippe Garot, MD

Institut Cardiovasculaire Paris-Sud (ICPS), Massy, France

Disclosure

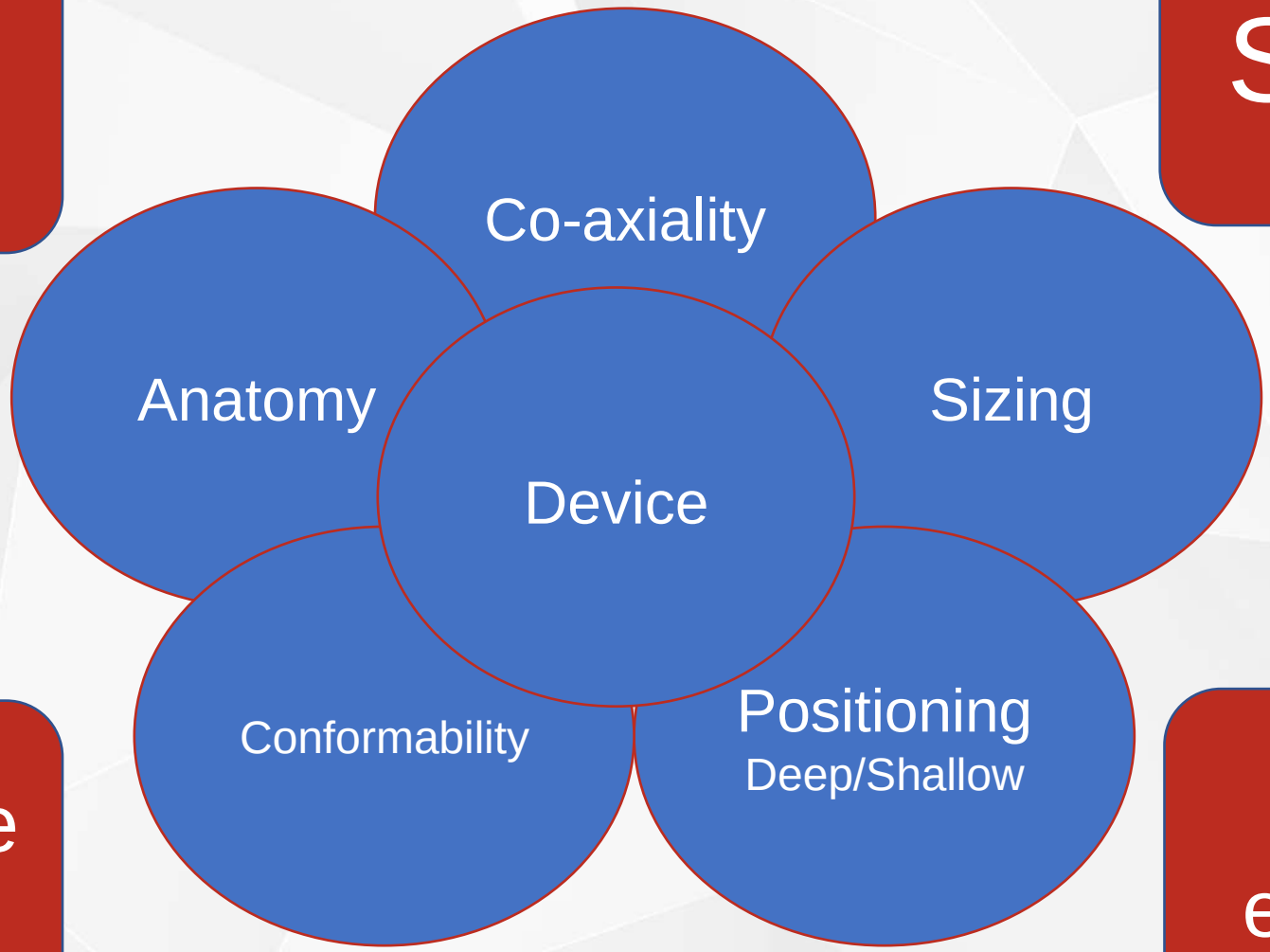
- No conflict of interest to discose for this presentation

Challenging procedures

PDL

DRT

Incomplete occlusion



Stroke

Tamponnade

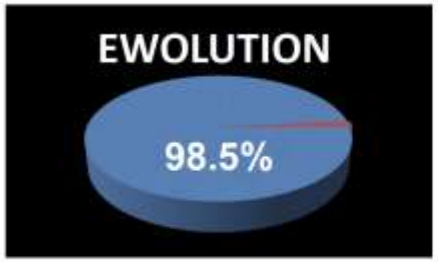
Device embolism

Procedural complications

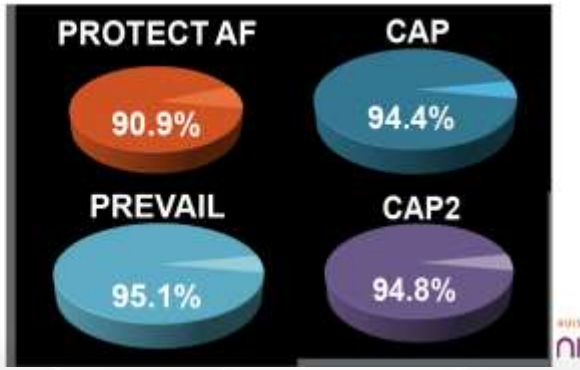
Challenging cases: Implant success rate & Peri-procedural related SAEs

EWOLUTION – Highest Implant Success

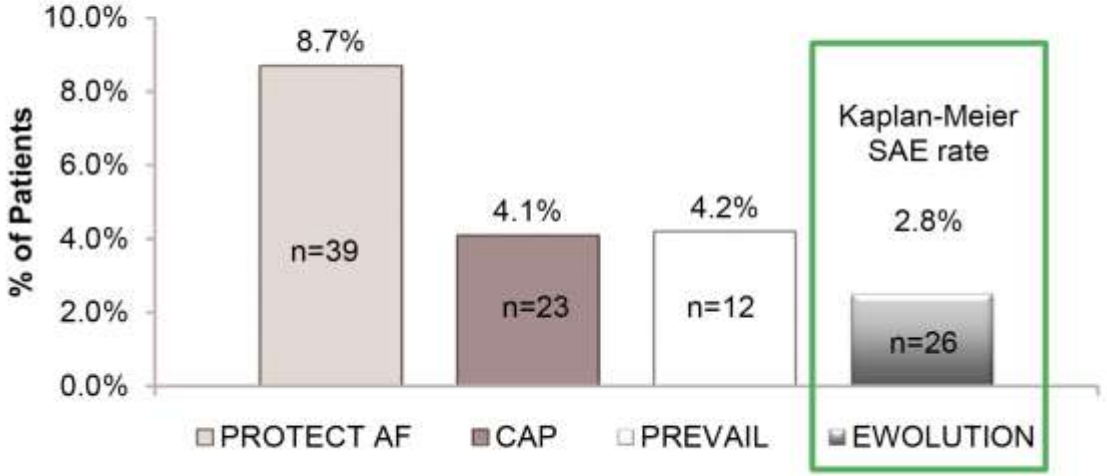
Study	Proportion	%	Fisher's Exact P-value
EWOLUTION	**1004/1019**	**98.5%**	-
PROTECT	408/449	90.9%	p<0.001
CAP	534/566	94.4%	p<0.001
PREVAIL	252/265	95.1%	p=0.002
CAP2	545/575	94.8%	p<0.001



Comparison of proportions between all studies: p=<0.001



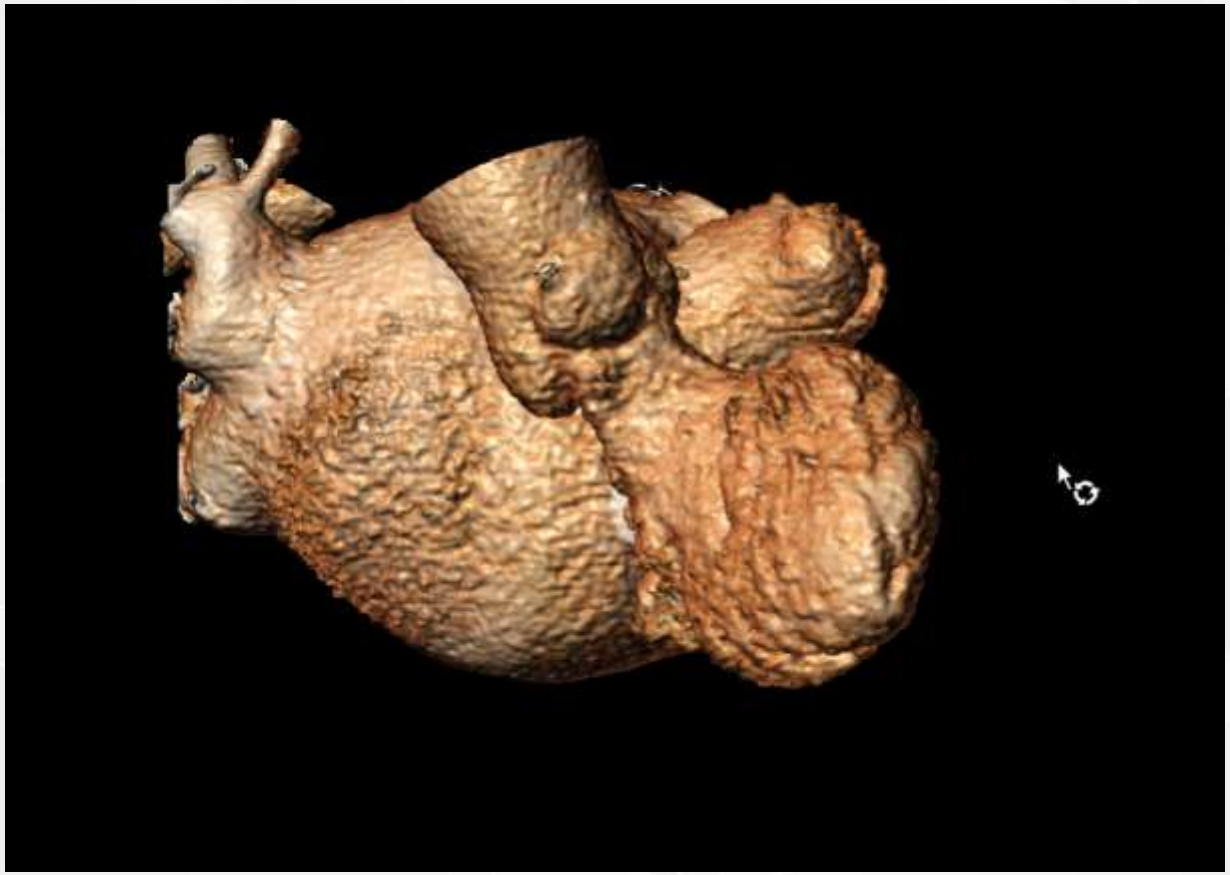
All Prior WATCHMAN studies: 7-Day Procedure/Device Related SAEs

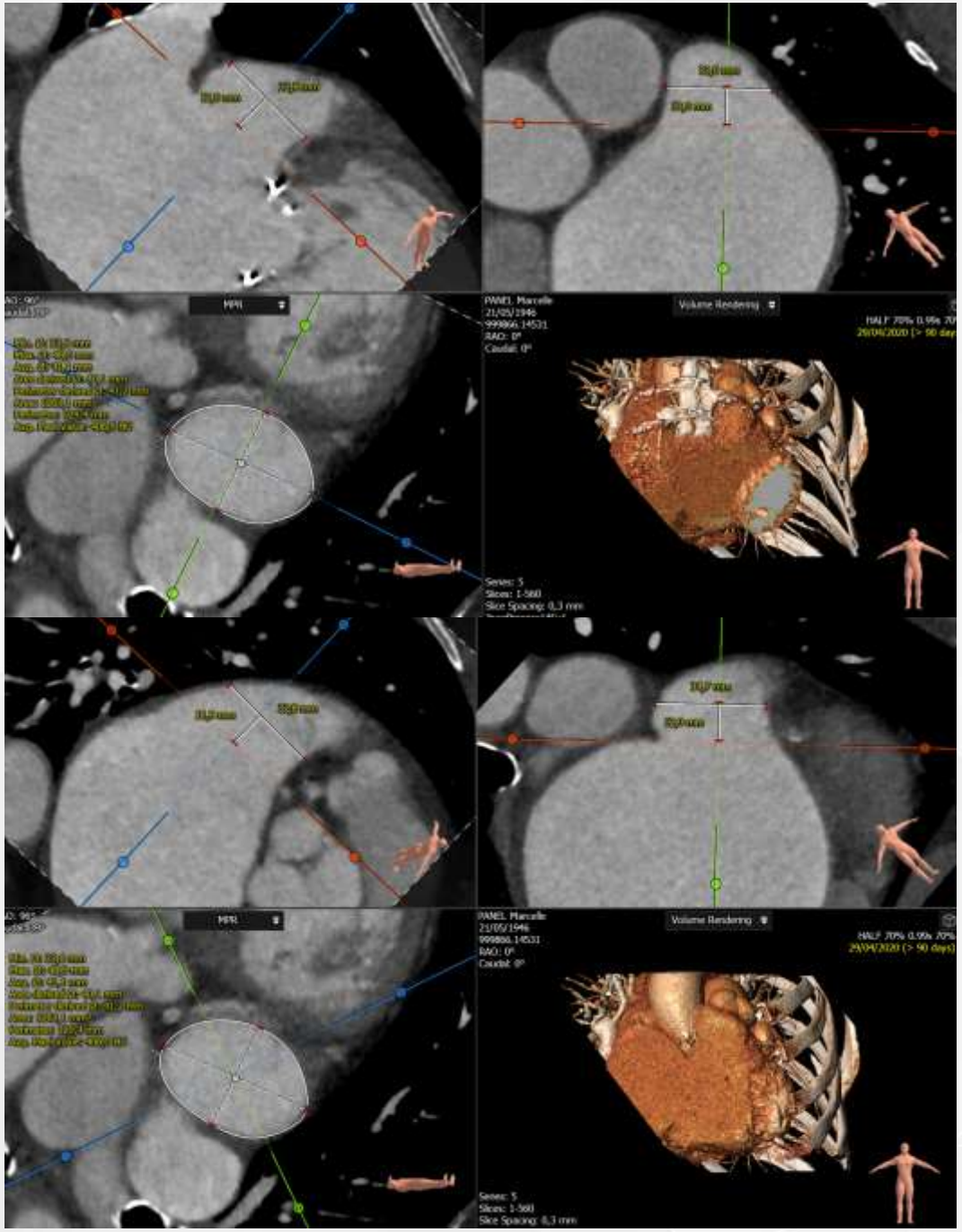


Composite of vascular complications includes cardiac perforation, pericardial effusion with tamponade, ischemic stroke, device embolization, and other vascular complications[1]

Advanced techniques and new devices to improve the results of challenging cases and decrease procedural complication rates

A case-based example of a large LAA





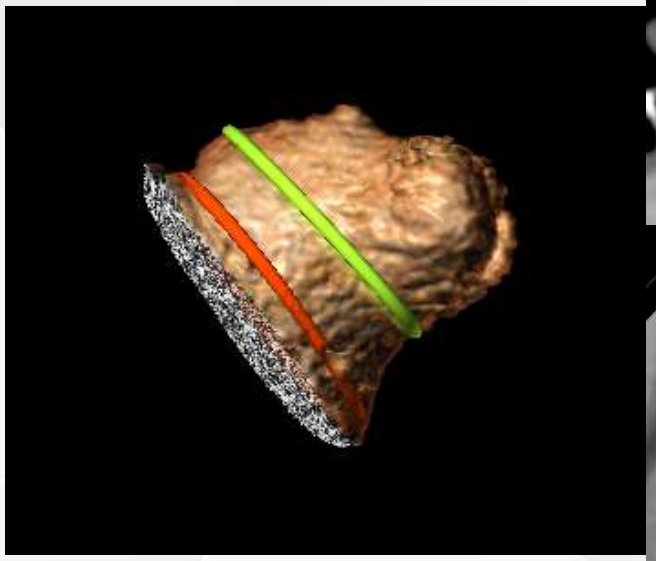
Ready to wear “Standard Sizing”?

Ostium (red):

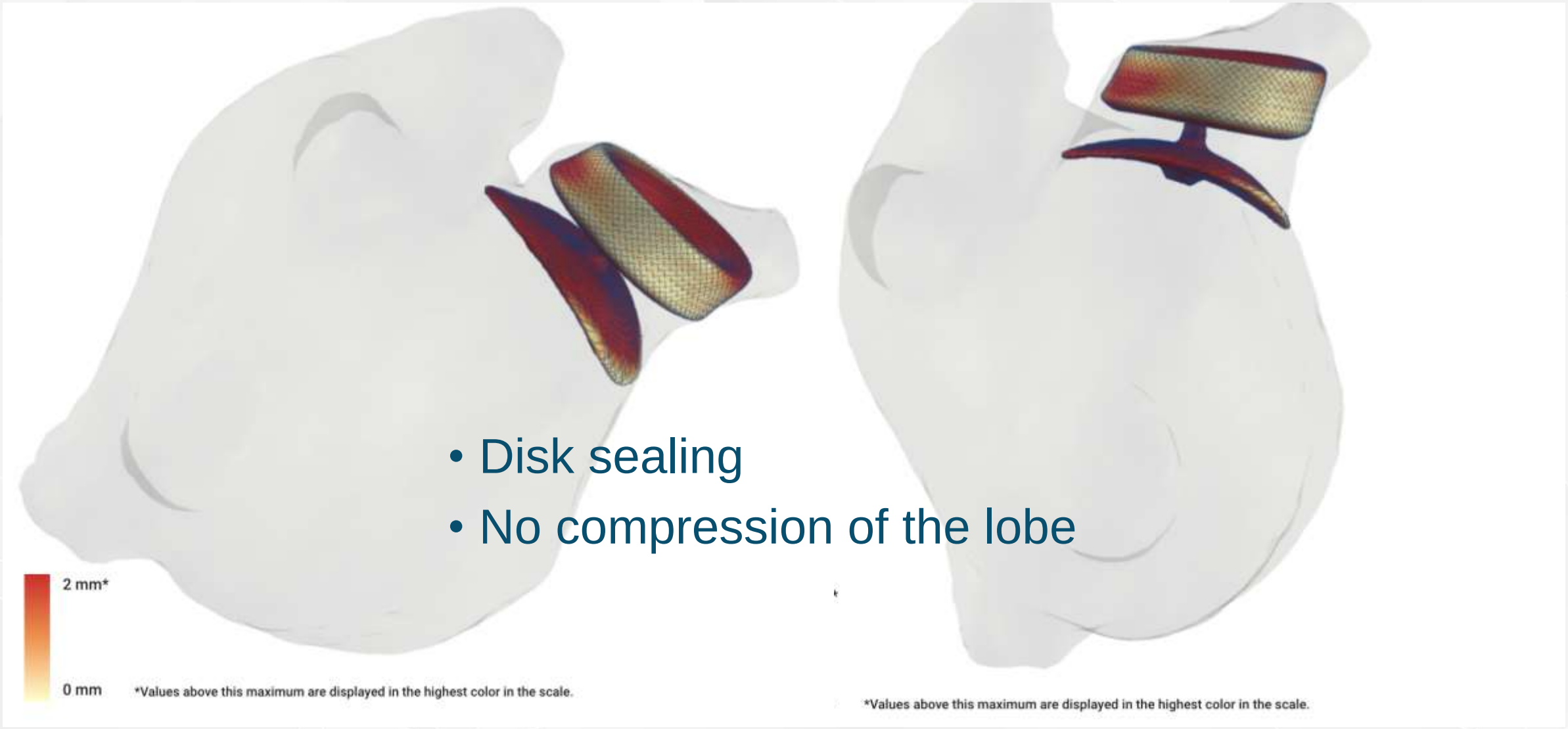
Min Ø:	34,3	mm
Max Ø:	46,2	mm
Avg Ø:	40,3	mm

Ostium (green):

Min Ø:	32,5	mm
Max Ø:	36,6	mm
Avg Ø:	34,5	mm

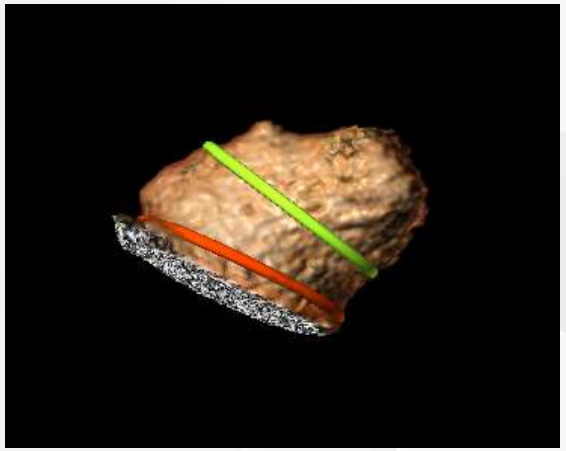


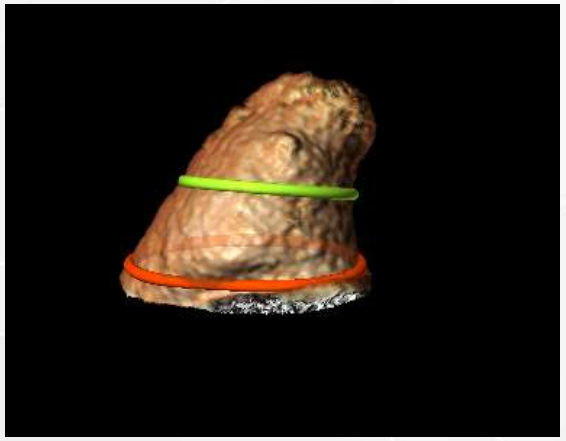
Computer-based simulation (Feops, Gent, BE)- Amulet 34



- Disk sealing
- No compression of the lobe

Tailored “Anatomical adjusted Sizing”



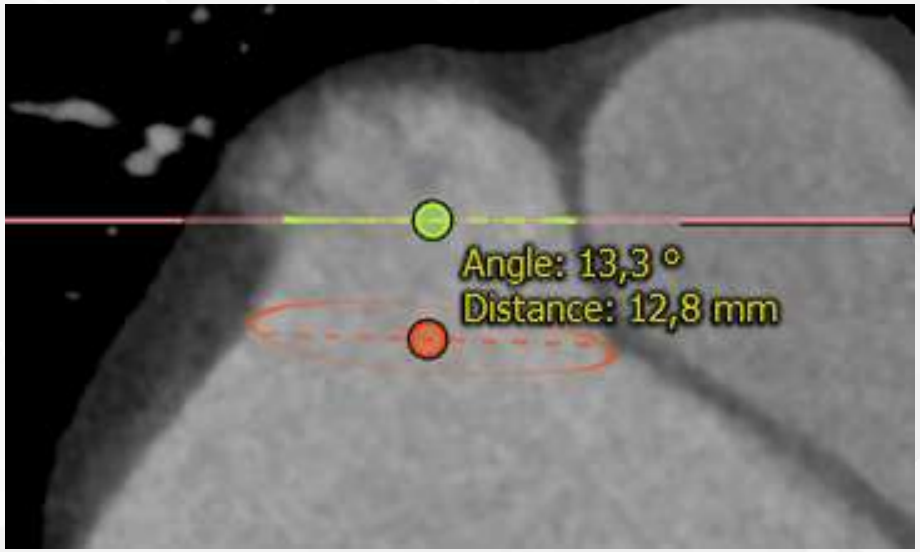


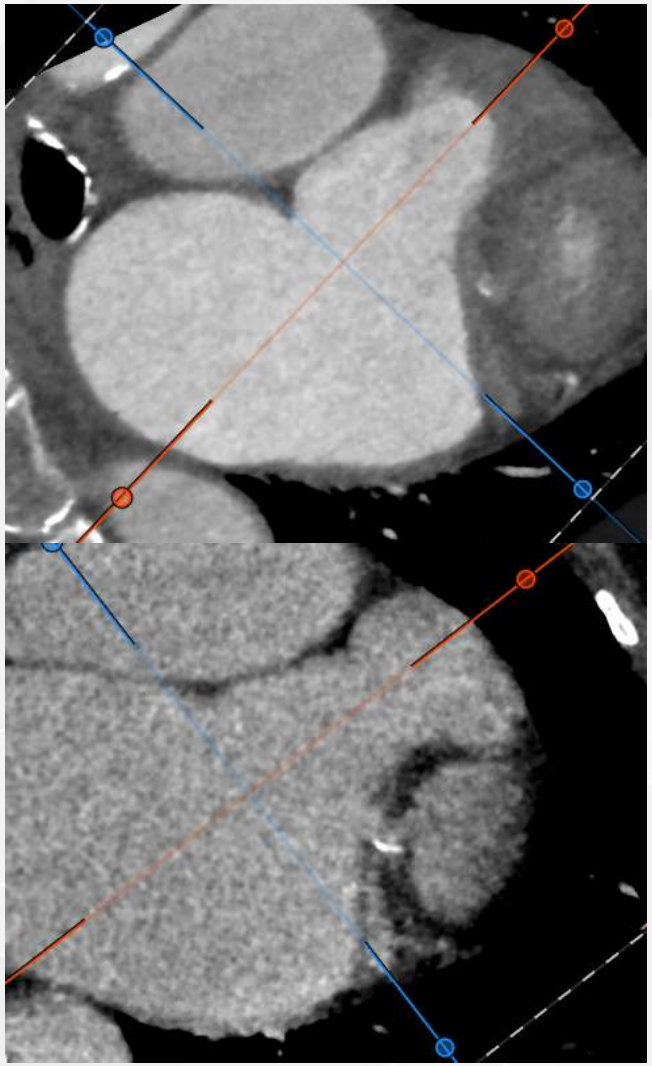
Ostium (red):

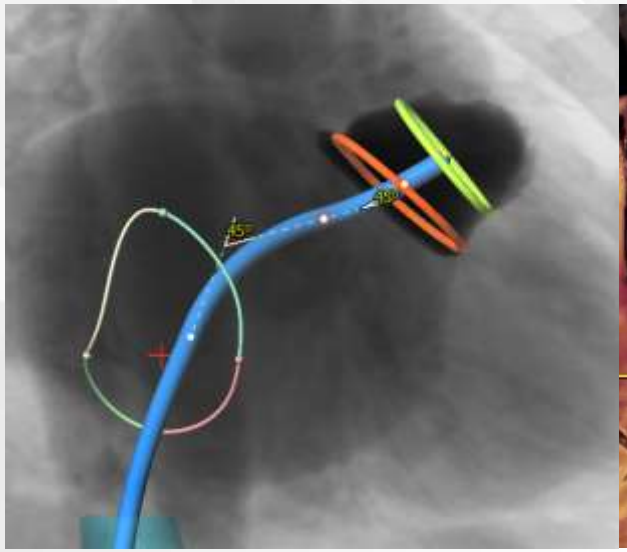
Min Ø:	32,8	mm
Max Ø:	39,1	mm
Avg Ø:	35,9	mm

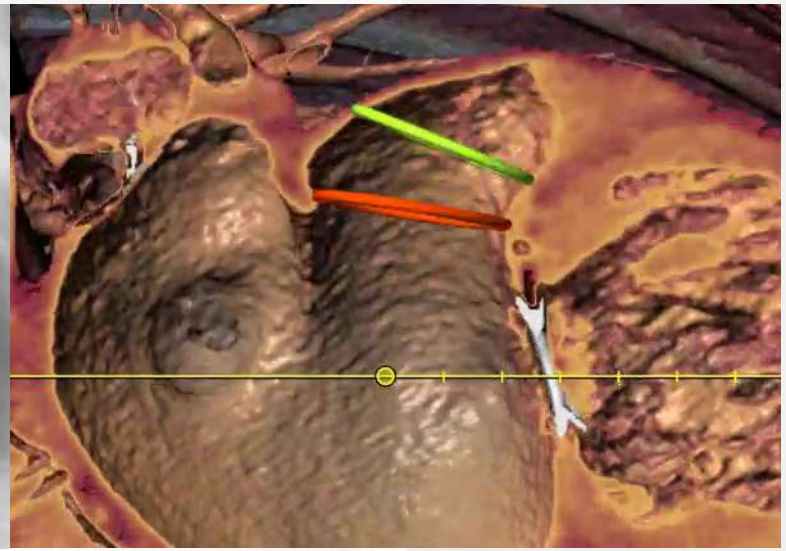
Ostium (green):

Min Ø:	27,6	mm
Max Ø:	32,1	mm
Avg Ø:	29,9	mm



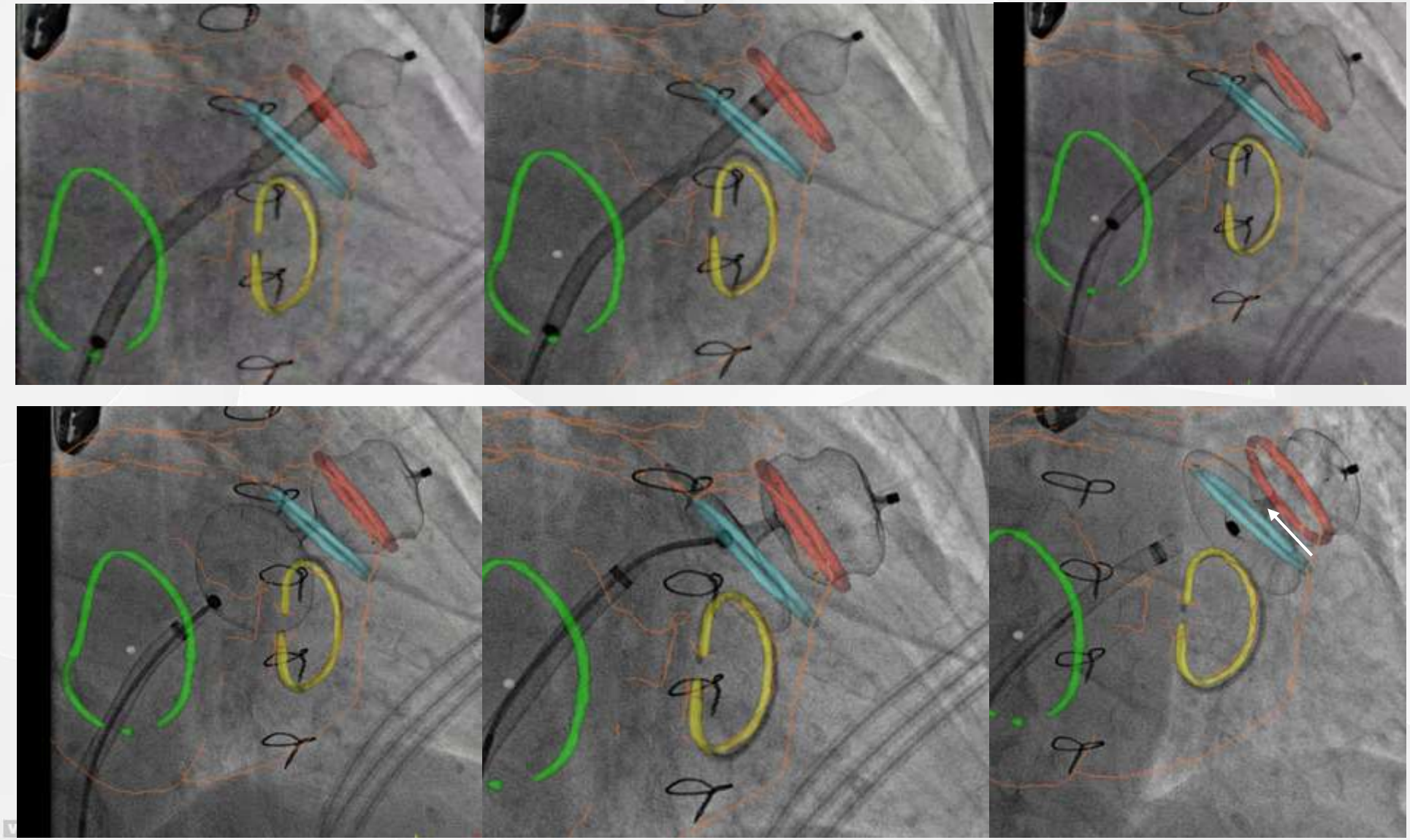




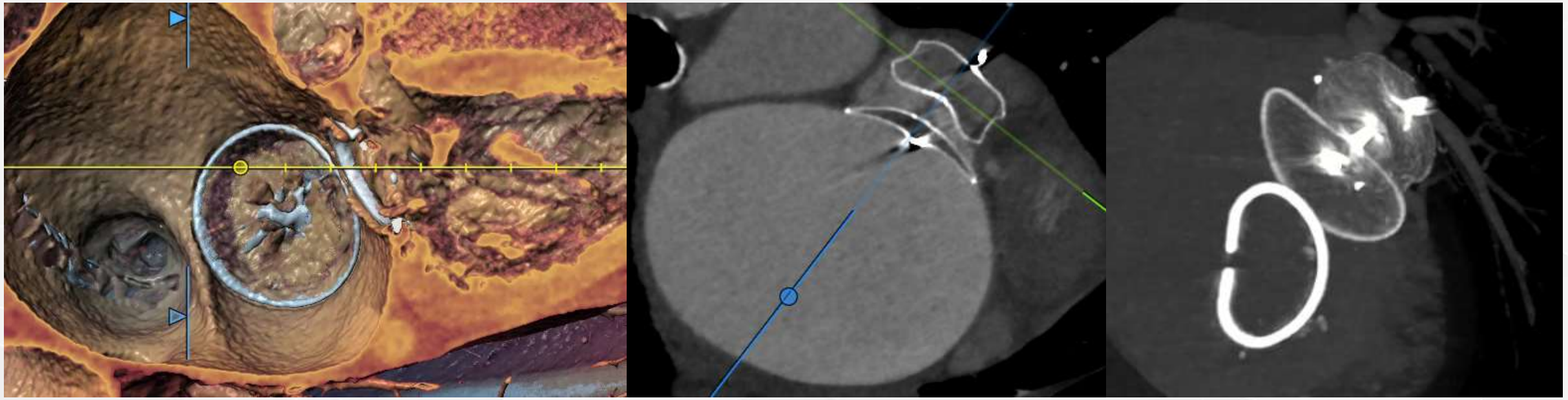


- LAA Ostium close to Mitral Ring
- Transeptal Puncture : inferior
- Sheath Orientation
- Angio projection : RAO 20°
- Distal implantation

Fluoro/CT fusion (ValveAssist® GE)



CT@6Mo



Advanced techniques

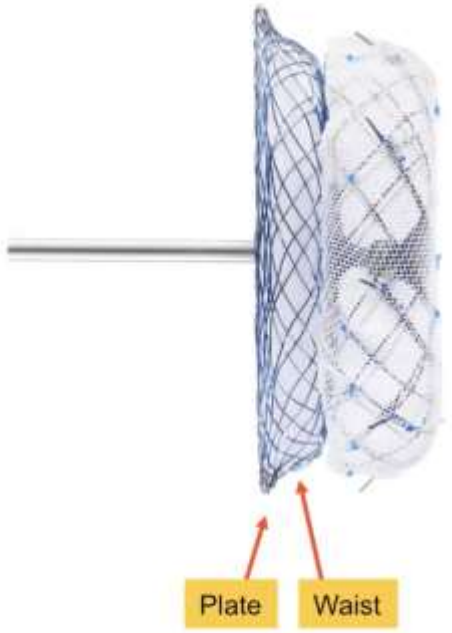
- Anticipate difficulties
- Case Planification
- Device sizing and positioning
- Facilitate the procedure
- Improve LAAO occlusion rates in complex cases

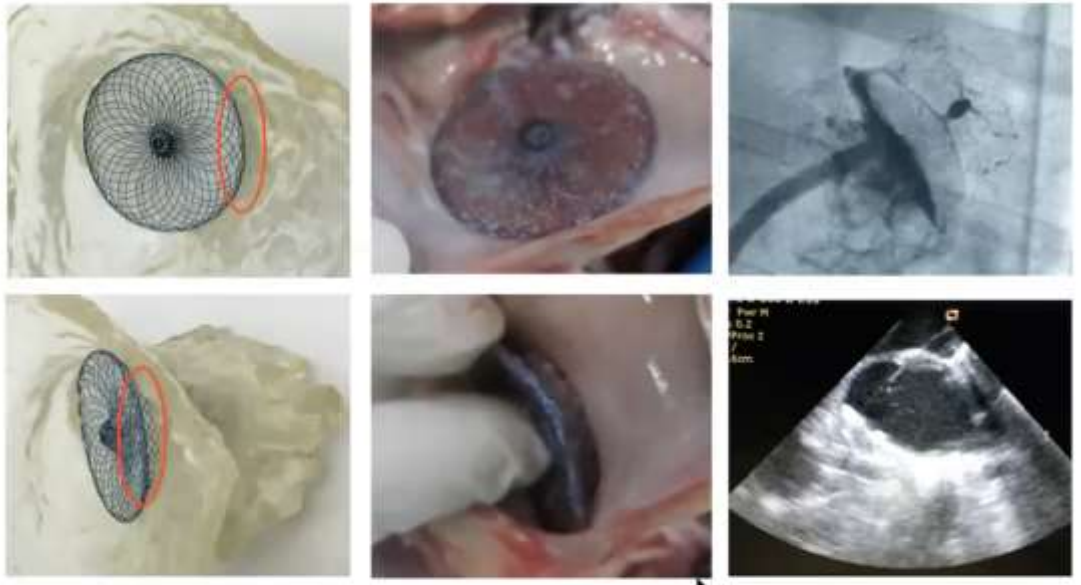
How new devices can overcome challenging procedures (Failure to implant/Periprocedural SAEs)?

SeaLA LAA Occluder
A plate and a waist: an additional seal disk

- 2 sealing lines for a better LAA occlusion
- Low profile delivery sheath
- Small but strong hooks
- Fully retrievable and repositionable

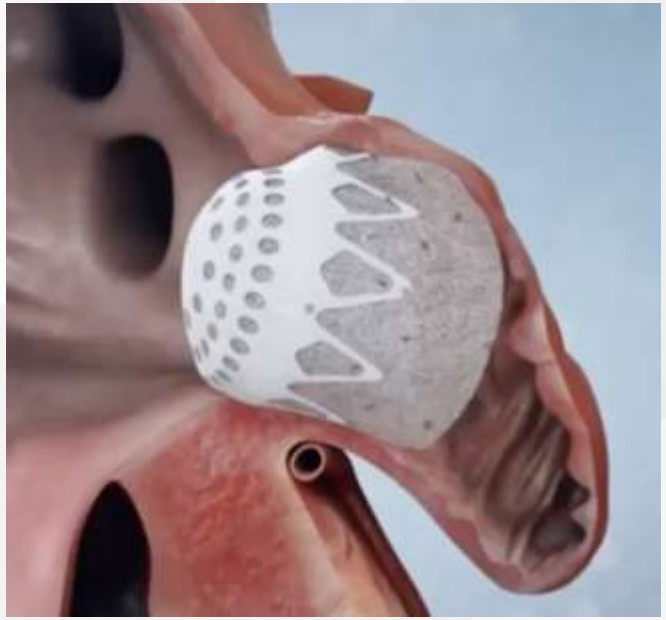
- CFDA Registry
  - Success 163/168
  - 12Mo PDL>3mm 0/152
  - DRT 4/152
  - Stroke 2/152





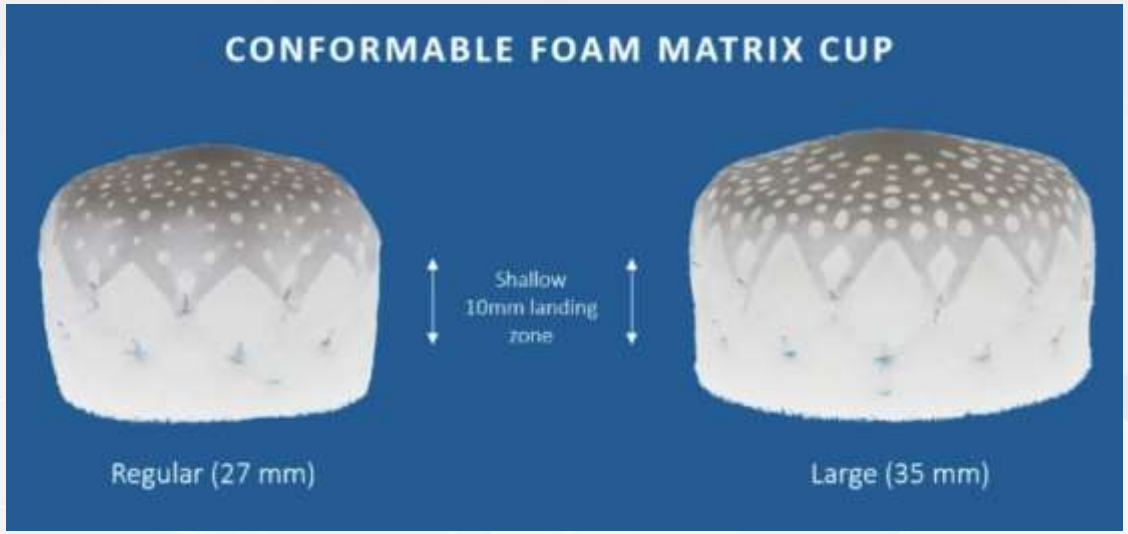
- If the Plate can't cover the LAA orifice completely, the waist can provide the second sealing line.

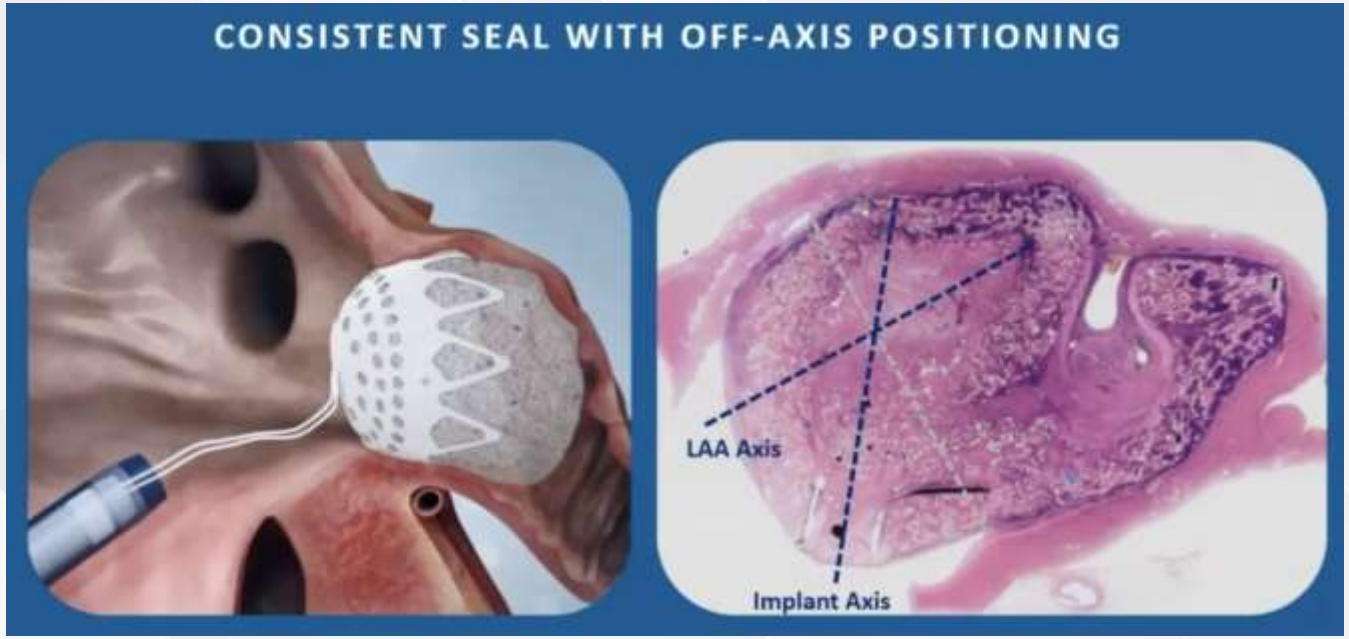
The Conformal LAA Seal - CLAAS implant Structure



Foam-based architecture
Designed to address the wide spectrum of LAA anatomies
2 sizes
No need of TEE/GA

The Conformal LAA Seal - CLAAS implant
Conform to all anatomies





The Conformal LAA Seal - CLAAS implant
Early feasibility study

PRAGUE single center study (N=15)

- Success 15/15
- LAA 11 to 28 mm
- No TEE
- No complication

US multicenter (4) study (N=22)

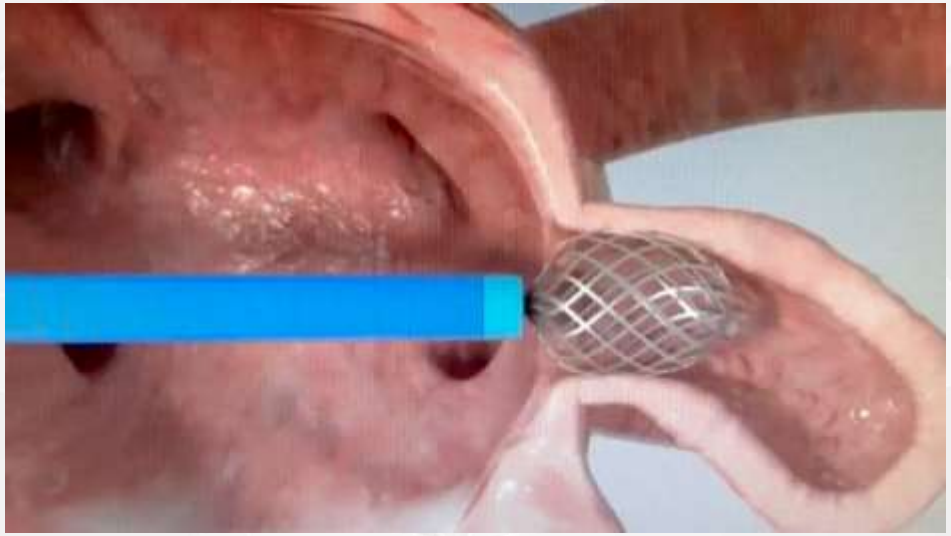
- Success 18/22 (4 LAA too large)
- LAA 9 to 31 mm
- TEE
- 2 leaks, 1 DRT

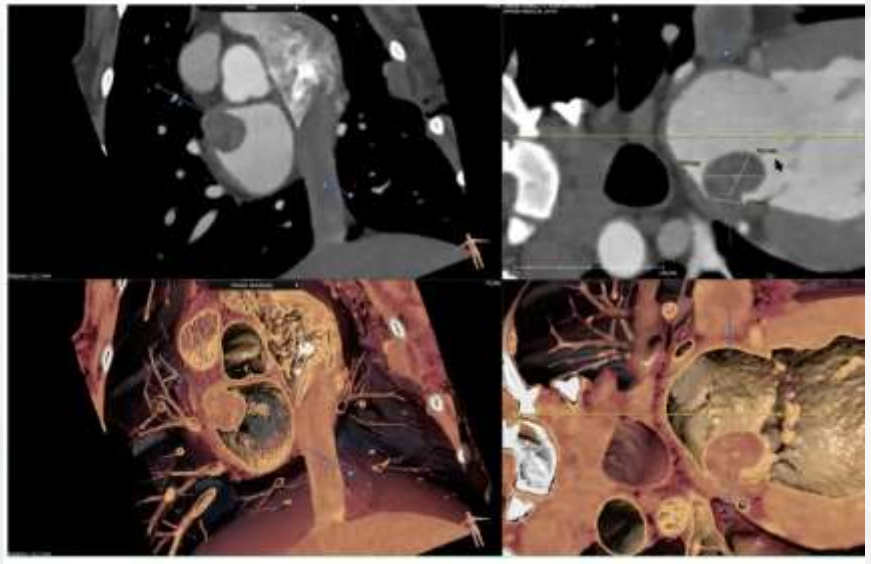
CONFORM Pivotal trial

- RCT CLAAS Vs. Watchman (1:1), prospective multi-center RCT
- 1,400 Pts (Recruitment about to start)
- Primary endpoint: 1-year clinical events, device seal
- Secondary endpoint: 18-Mo stroke and systemic embolism

The Appligator™

- LAA Closure without implant
- Seems simpler than device closure (No need for LAA measurements, One size fit all)
- Simpler than transpericardial LAA closure
- Complete sealing (invagination)





Endomatic Closure

- Non thrombogenic
- Fits all anatomies
- Suturing-like hermetic sealing

- Device closure without leaving the device exposed to the blood
- No device embolization
- No DRT

Conclusion / Take-home Message

- **Multimodal imaging capacities (CT+++)**
  - 3Mensio
  - XR/CT or TEE/XR Fusion
  - Feops computer-based simulation
  - 3D-printing

  Help the procedure with dedicated planification (positioning/sizing/anticipate difficulties)

- **New devices**
  - Better sealing
  - Conform to all (?) anatomies
  - “No-implant” LAA Occluders