

# Novel Conformable Foam-Based Implant for Left Atrial Appendage Closure: Conformal EFS Experience

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# Disclosure Statement of Financial Interest

I, **William A. Gray, MD**, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Faculty disclosure information can be found on the app

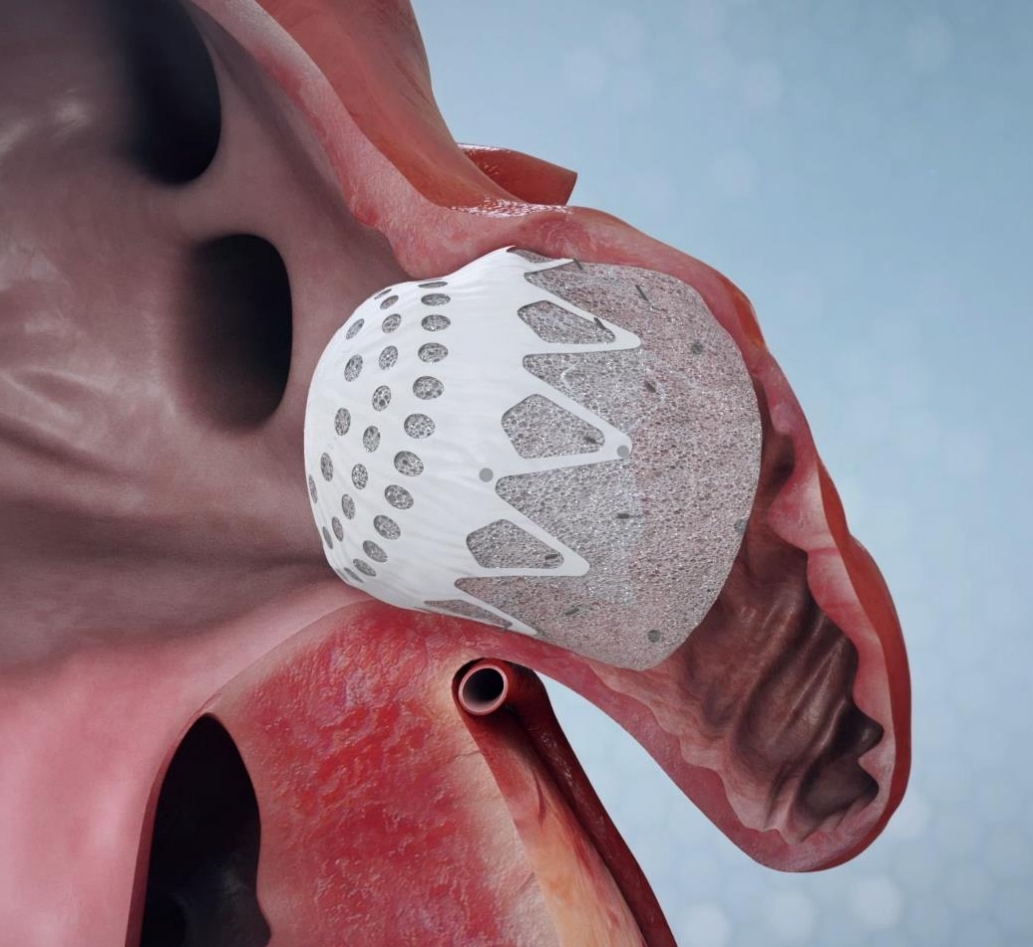
# US Conformal Early Feasibility Study (EFS)

Conformal Medical's  
**CLAAS<sup>®</sup> Implant**

EFS IDE, First-in-Human

Single arm, multi-center (4)  
feasibility study





## Conforms to a variety of LAA sizes and shapes

- ✓ Consistent seal
- ✓ Simple delivery
- ✓ Designed to reduce DRT

# Conformal CLAAS Device

CONFORMABLE FOAM MATRIX CUP



Regular (27mm)



Shallow  
10mm landing  
zone



Large (35mm)

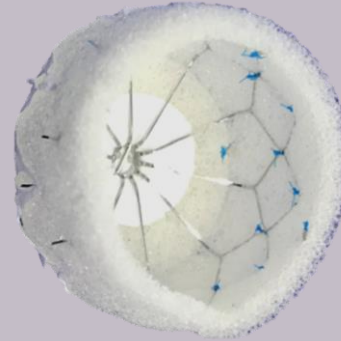
2 sizes intended to cover  
majority of LAA configurations

# Conformal CLAAS Device

DESIGNED TO MINIMIZE THROMBUS



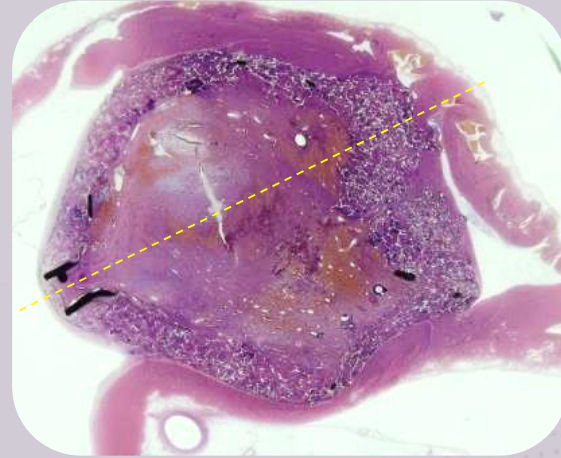
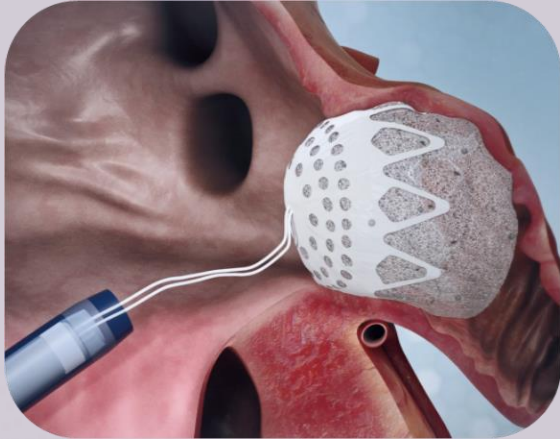
**Flexible tether**  
eliminates cable attachment site



**ePTFE cover**  
less thrombogenic

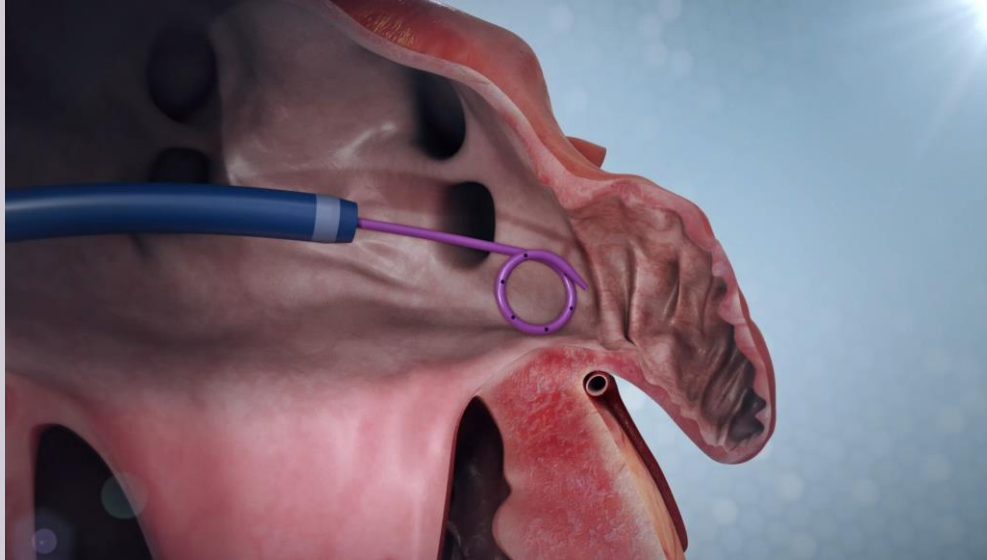
**Compliant nitinol**  
endoskeleton

# Consistent Seal with Off-Axis Positioning





# Conformal CLAAS Procedure

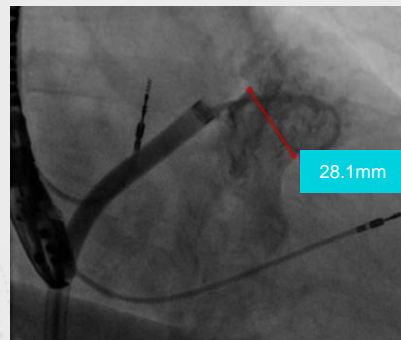
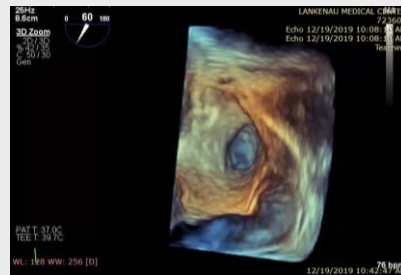




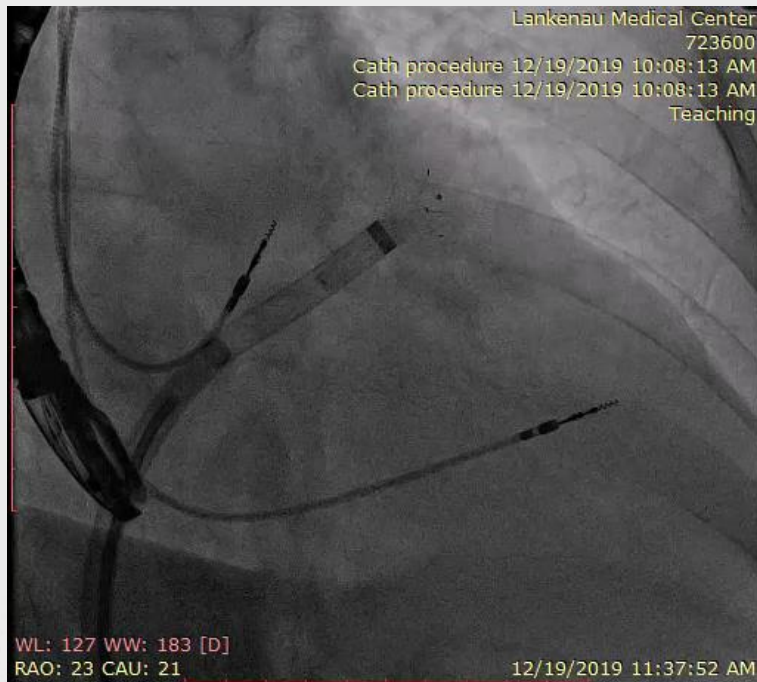
# Case Example: Large, Shallow LAA

- 71 y/o F
- Hx of GIB
- CHA<sub>2</sub>DS<sub>2</sub>VASc 3
- TEE measured
- Dia<sub>max</sub>: 25mm
- Dia<sub>min</sub>: 15mm
- Depth: 19mm

Patient 1801-05

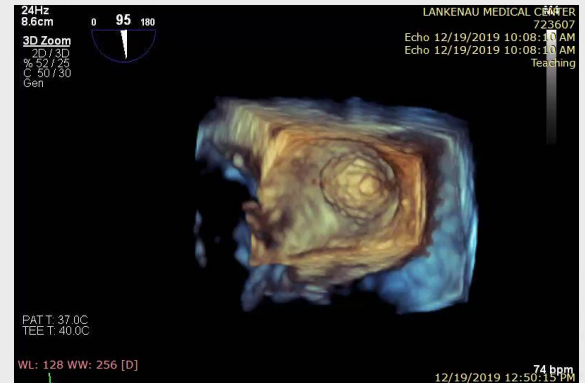
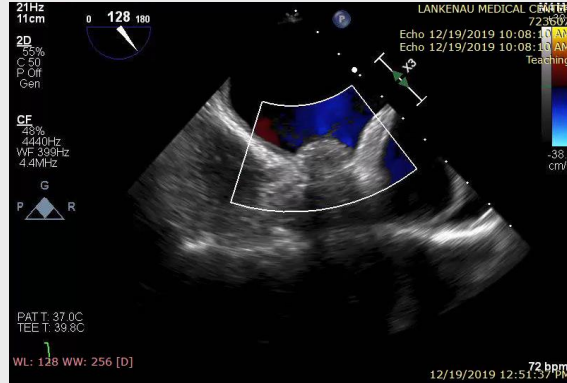
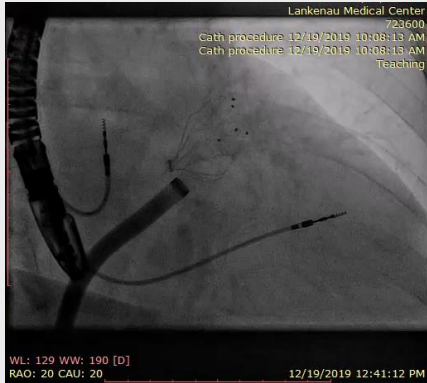


# Deployment



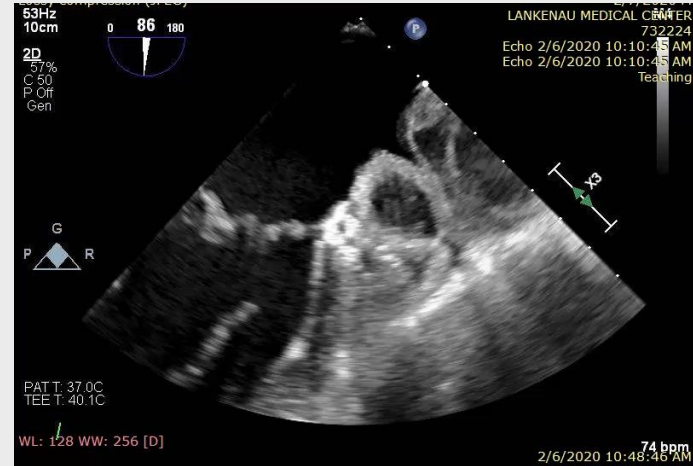
Patient 1801-05

# Post-Release



Patient 1801-05

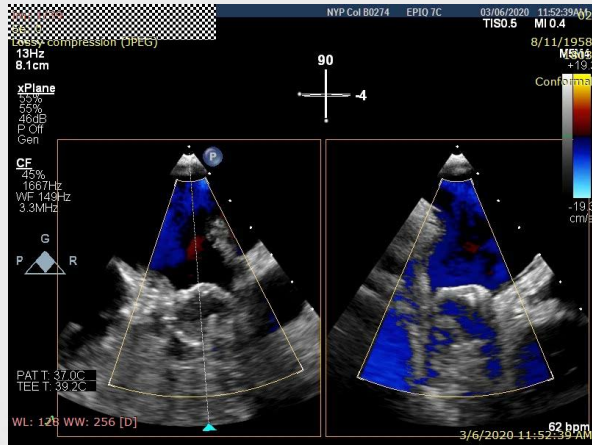
# 45 Day TEE



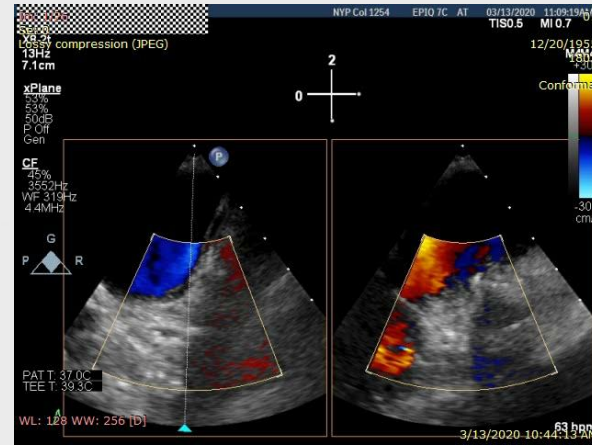
Patient 1801-05

# 1-Year FU TEEs

Patient 1803-01



Patient 1803-02



# US EFS Study Results\*

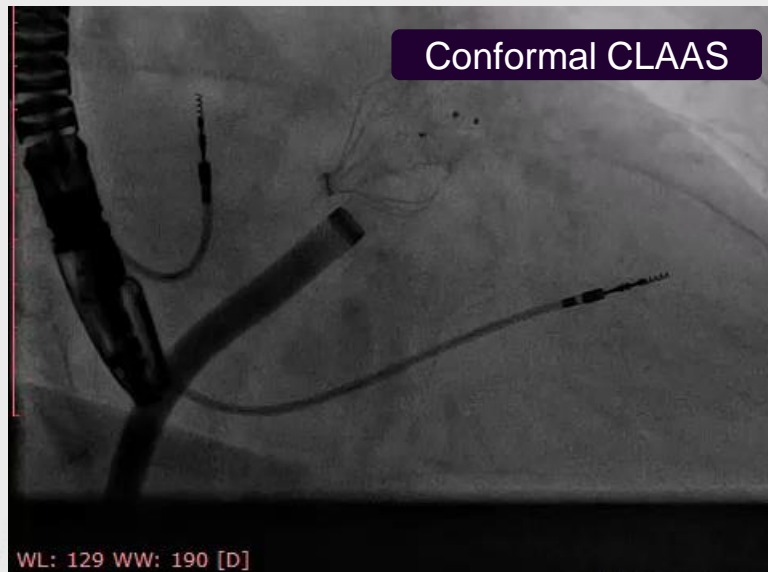
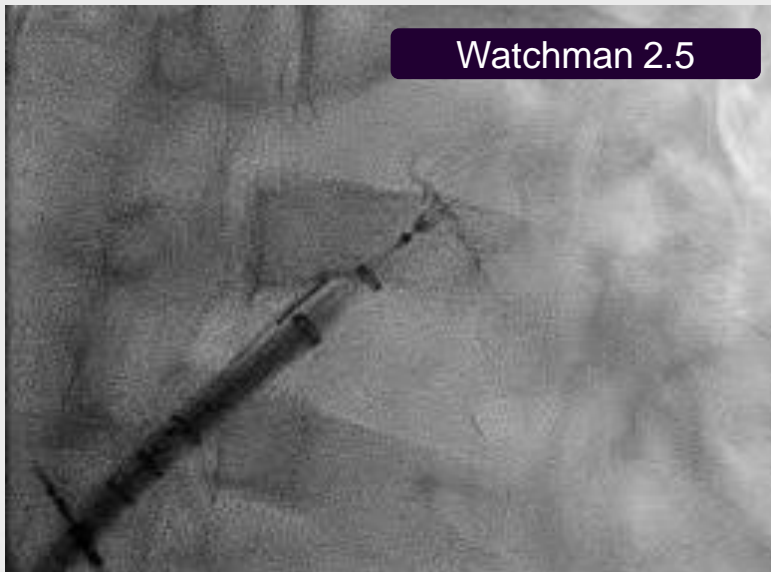
Enrolled Patients	22
Successful Implants	18 (4 LAA's too large for regular implant)
Age	74.0 ± 8.7 years
CHA <sub>2</sub> DS <sub>2</sub> -VASc	4.4 ± 1.7
Device Procedural Complications	0
FU (45D, 6M, 1YR)	20, 15, 4
LAA Diameters (Mean/Range)	18.7 ± 3.5 mm (9.1-30.7 mm)
Conformal Sizes Used (n)	17 Regular, 1 Large
Leaks (45D)	2 (10mm missed lobe, 1mm)
Device Related Thrombus (45D)	1

\*As of Sept 23, 2020



# Conformal CLAAS Design

ePTFE COVER ALLOWS FOR LEAK DETECTION WITH ANGIOGRAPHY





# Conformal CLAAS EFS: Conclusions

- CLAAS LAAO system has shown feasibility and safety
  - TEE shows conformability with encouraging sealing results
- Only 2 sizes address large range of LAA anatomies
- EFS continuation and Pivotal trial anticipated 2021

# Conformal Next Steps

## EFS Continuation Study

- Prospective, single-arm, multicenter study
- Evaluate Gen 2 Delivery System
- Validate pivotal device delivery protocol
- N ~ 30
- First patient: Q1 2021

## Pivotal Trial

- RCT: Conformal CLAAS vs. Watchman/FLX 1:1, n ~ 1,400
- Primary endpoint: 1-year clinical events, device seal
- Secondary endpoint: 18-month stroke & systemic embolism
- First patient: Q2 2021

**Thank you**