ICE-Guided LAA Closure with a Conformable Foam Implant

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- Conflicts of Interest:
  - *Grant support and/or Consultant*: Abbott, Biosense-Webster & Boston Scientific
  - Study funded by Conformal Medical Inc.
- This presentation discusses FDA-unapproved devices.

Disclosures

- Consultant and/or Grant support:

  Abbott, Ablacon*, Acutus Medical*, Affera*, Apama Medical*, Aquqheart*, Atacor*, Autonomix*, Axon*, Backbeat*, Biosense-Webster, Biosig*, Biotronik, Boston Scientific, Cardiofocus, Cardionomics, CardioNXT/AFTx, Circa Scientific*, Corvia Medical*, Dinova-Hangzhou Nuomao Medtech*, East End Medical*, EBR, EPD*, EPIX*, EpiEP*, Eximo*, Farapulse*, Fire1, Impulse Dynamics, Intershunt*, Javelin*, Kardium*, Keystone Heart*, LuxMed*, Manual Surgical Sciences*, Medlumics*, Medtronic, Middlepeak*, Newpace*, Nuvera*, Phillips, Pulse Biosciences, Sirona Medical*, Surecor*, Thermedical, Valcare*, Vizaramed*

  * I have an equity stake in these companies

- I will be discussing investigational devices without FDA or CE-Mark approval.

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Conformal Prague Early Feasibility Study (EFS)

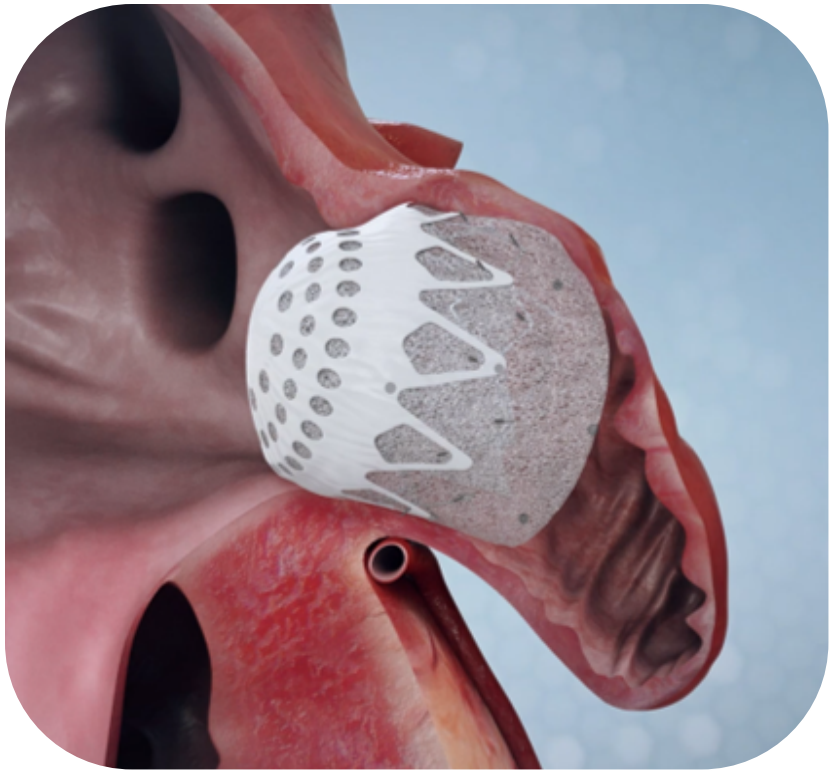
Conformal Medical's
CLAAS implant

Single-arm, single-center
ICE feasibility study

First-in-human, n=15

STUDY PROCEDURE FLOW:

1. Conscious sedation
2. ICE in RA
3. Trans-septal
4. ICE in LA
5. Fluoroscopy-/ICE-guided placement of the LAAC device
6. TEE confirmation
7. LAAC device release



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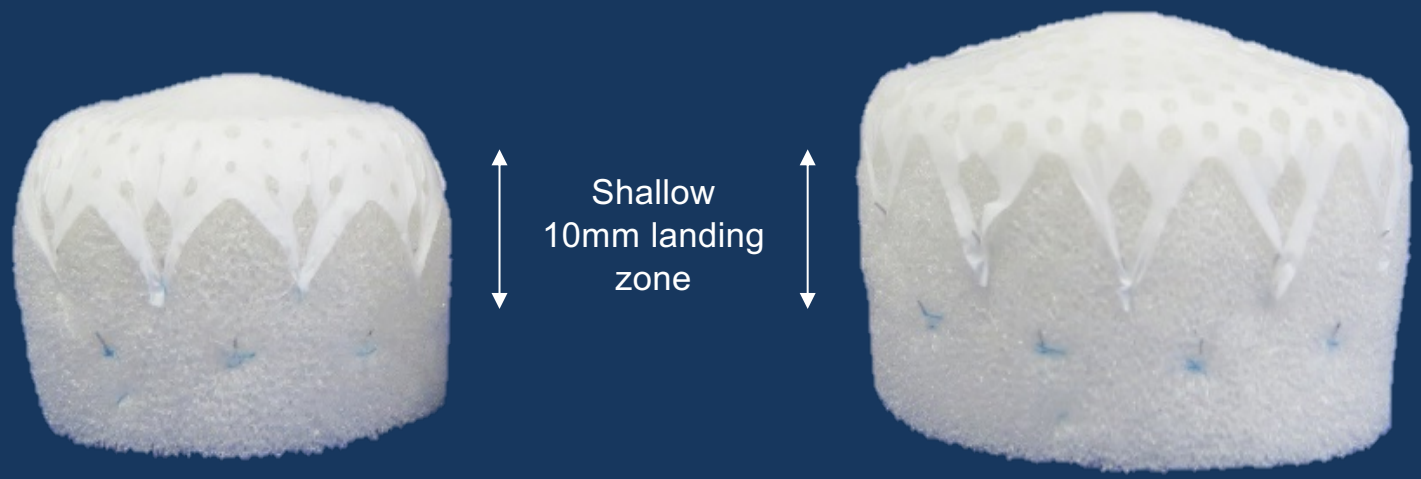
Conformal LAAC Device

Conformal Foam Matrix Cup



Two sizes to address all LAA anatomies

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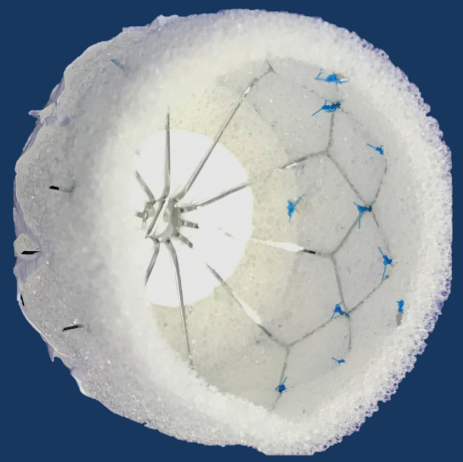
Conformal LAAC Device

Designed to Attempt to Minimize Thrombus



Flexible tether	ePTFE cover	Compliant nitinol endoskeleton
eliminates cable attachment site	less thrombogenic	

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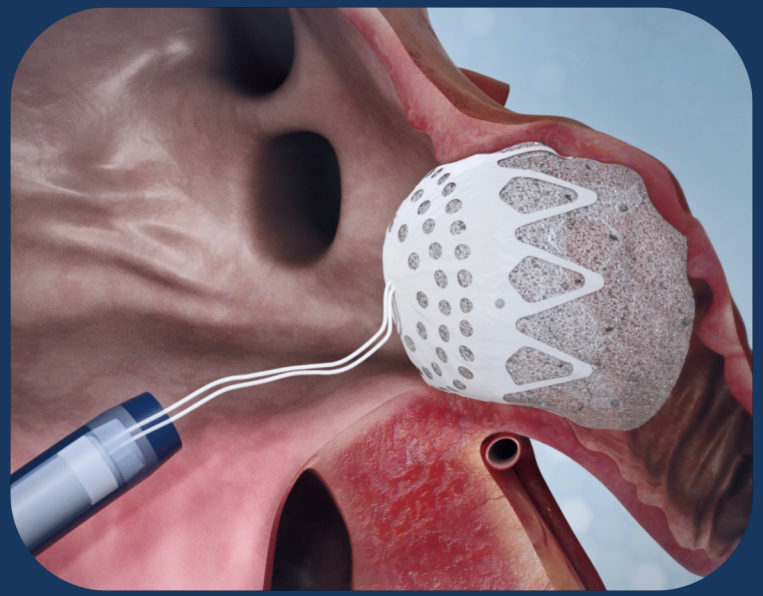
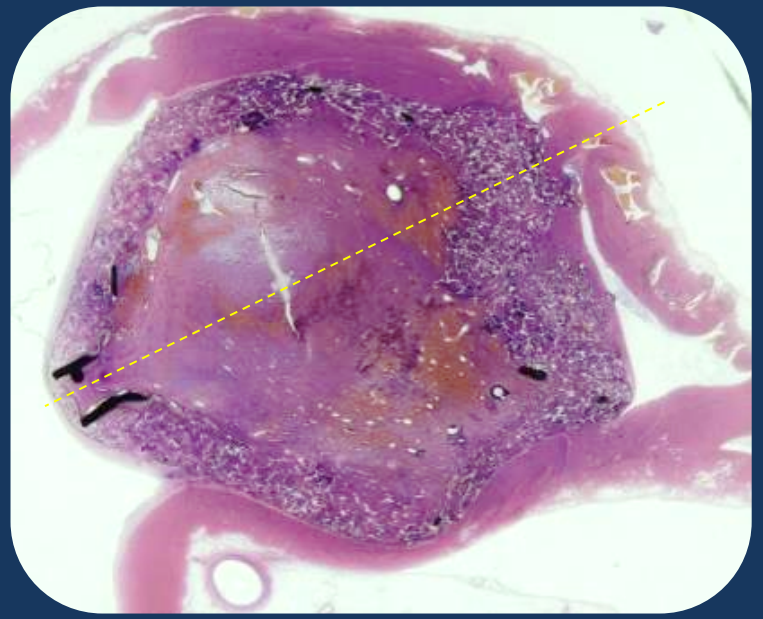
Allows Seal Despite Off-Axis Positioning





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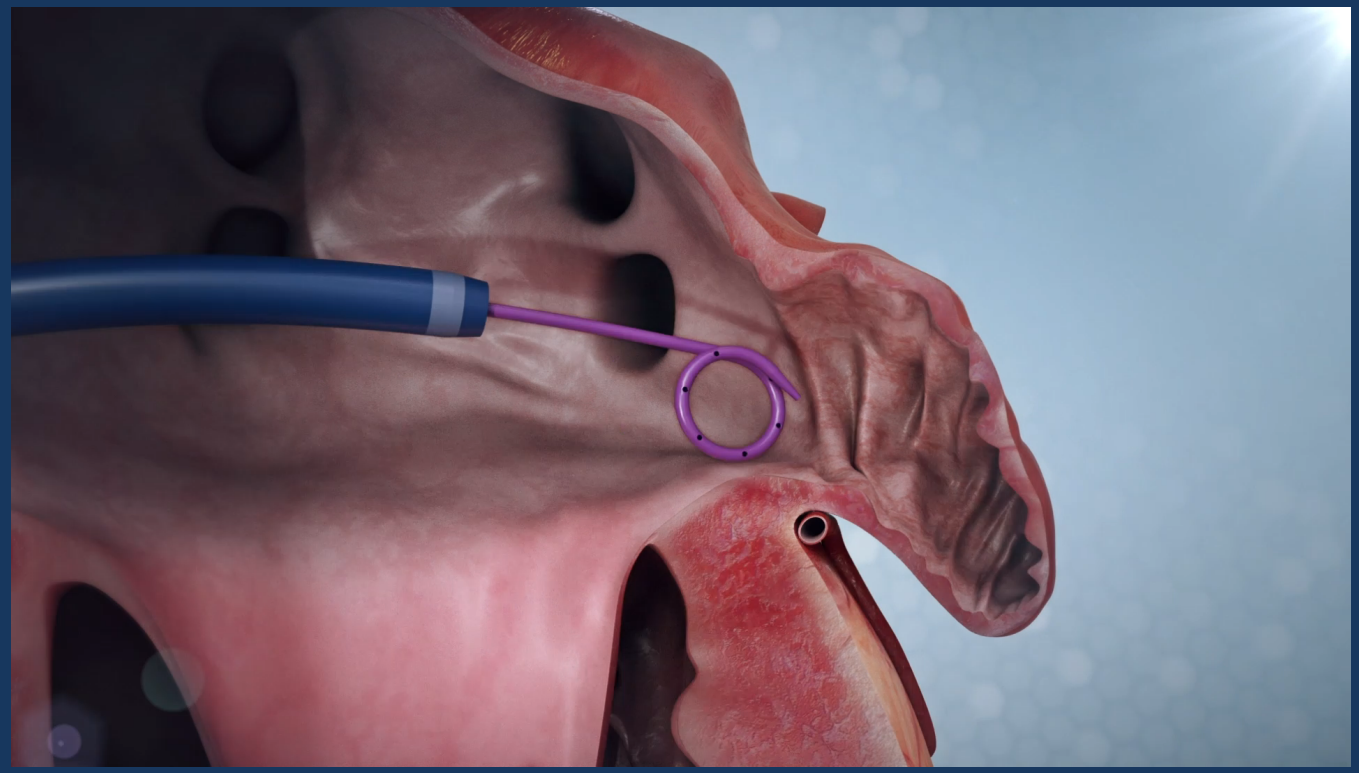
Conformal CLAAS Procedure



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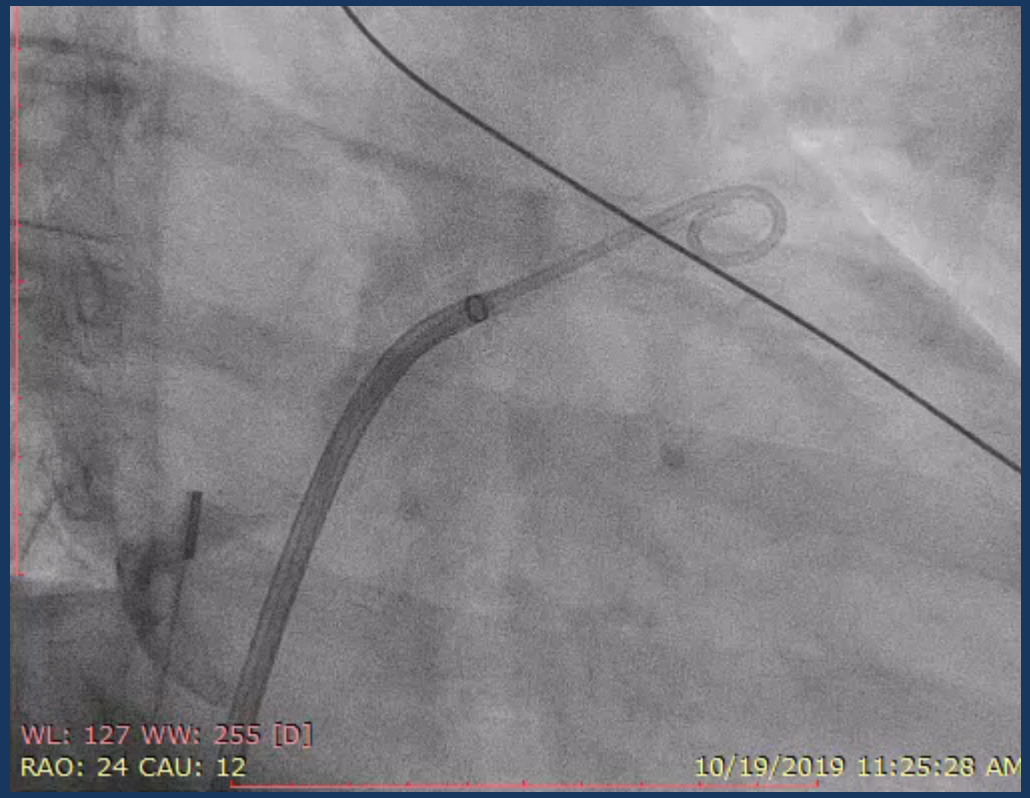
Conformal Prague-EFS ICE Study

Baseline Assessment

- 77 y/o F Hx of falls (CHA_2DS_2-VASc 5)
- TEE evaluation: 17 x 20 mm
- Implant size: regular

Patient 1901-02



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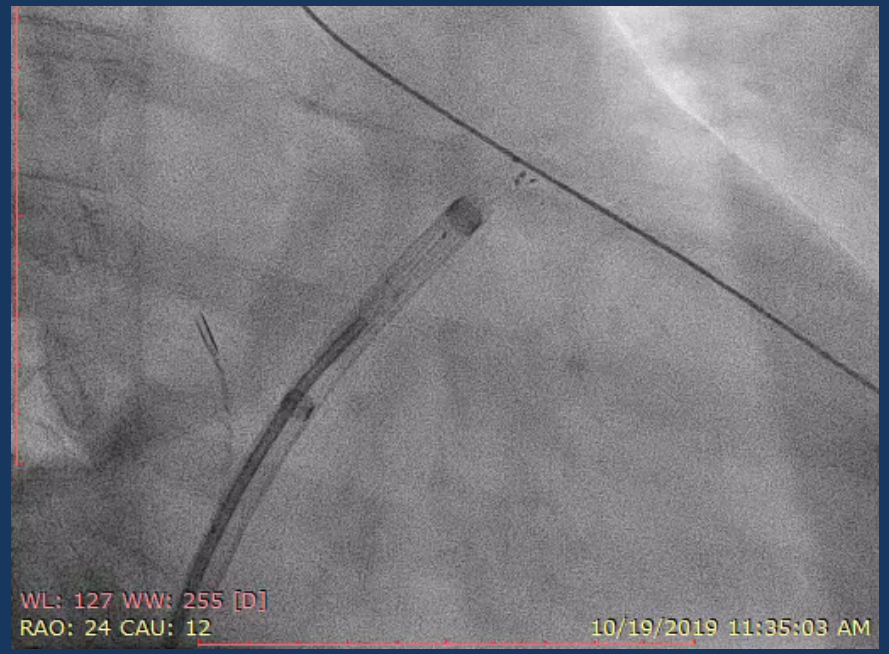
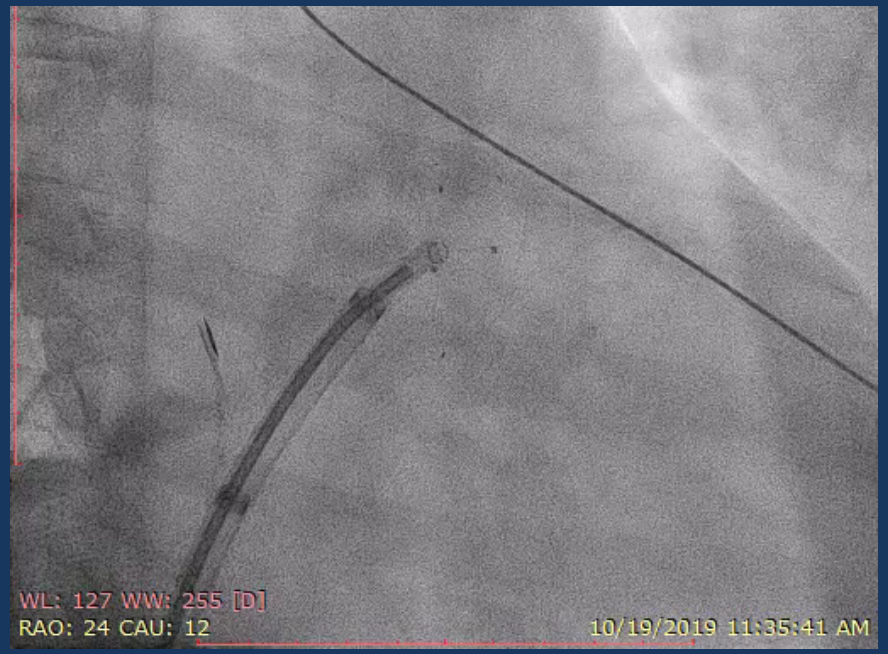
Placement & Recapture

Initial Placement (too deep)



Recapture



Patient 1901-02

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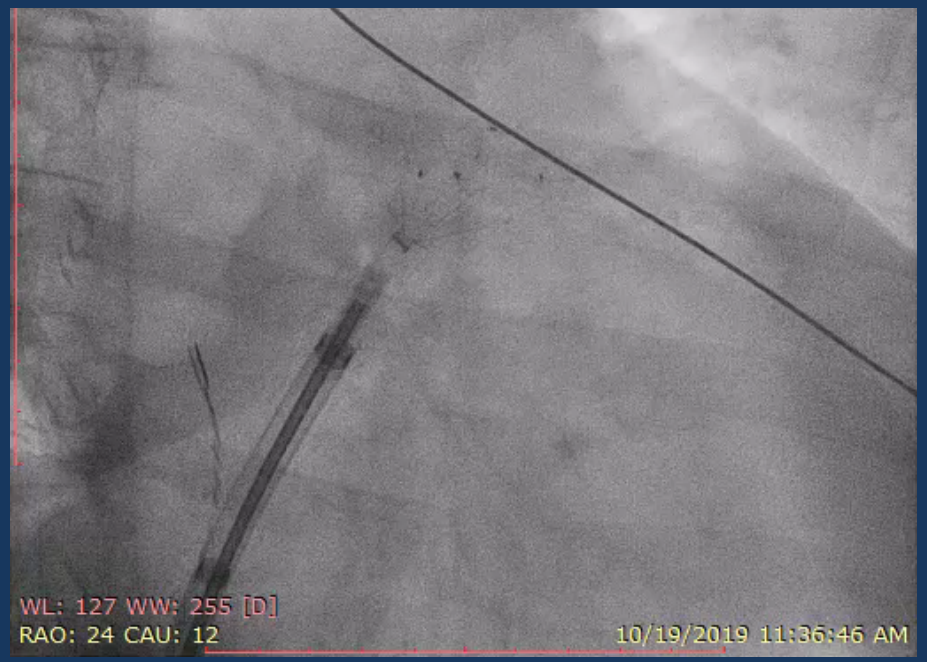
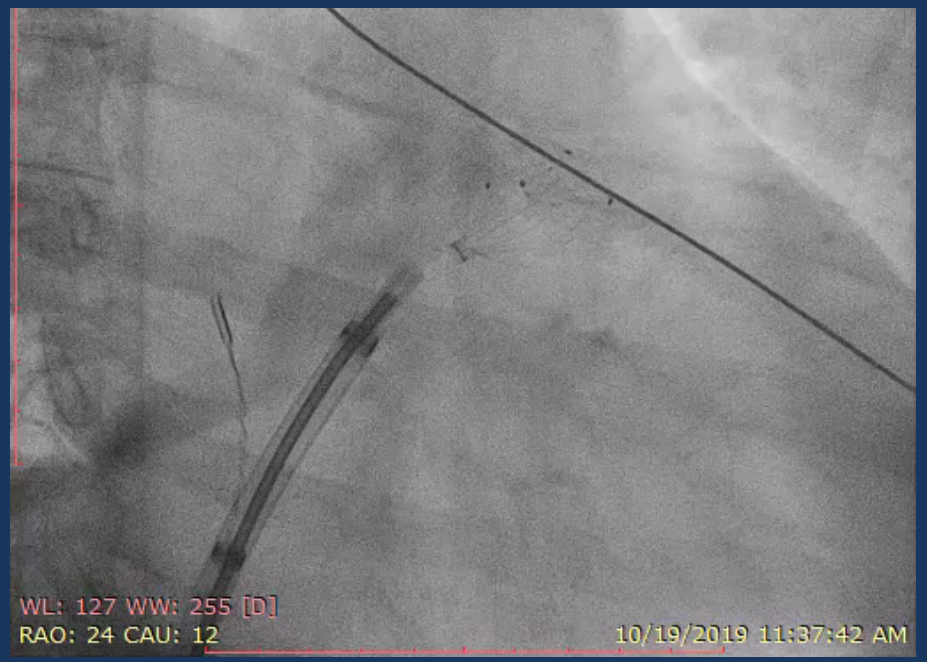
Pre-Release Assessment

Tug Test



Patient 1901-02

Angio: Seal Assessment



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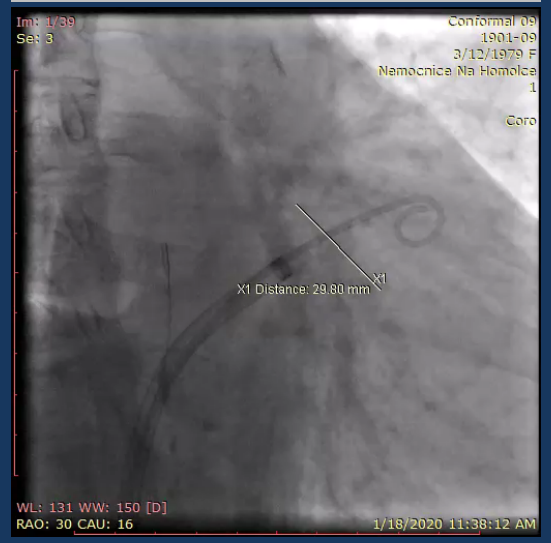
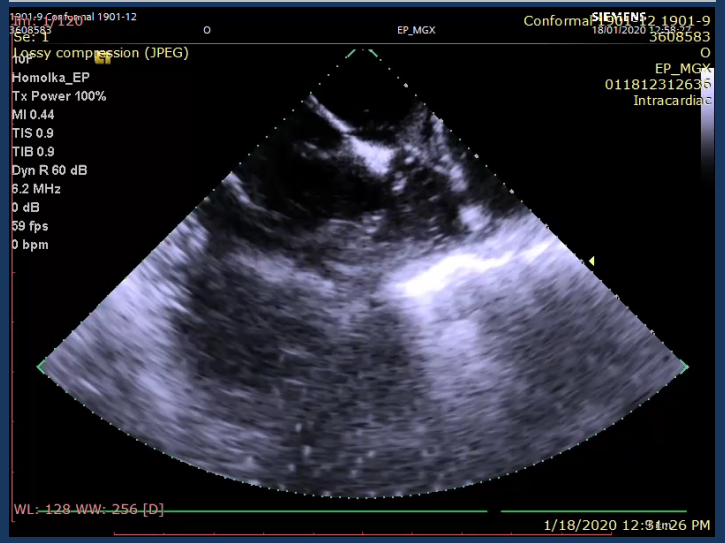
ICE Evaluation

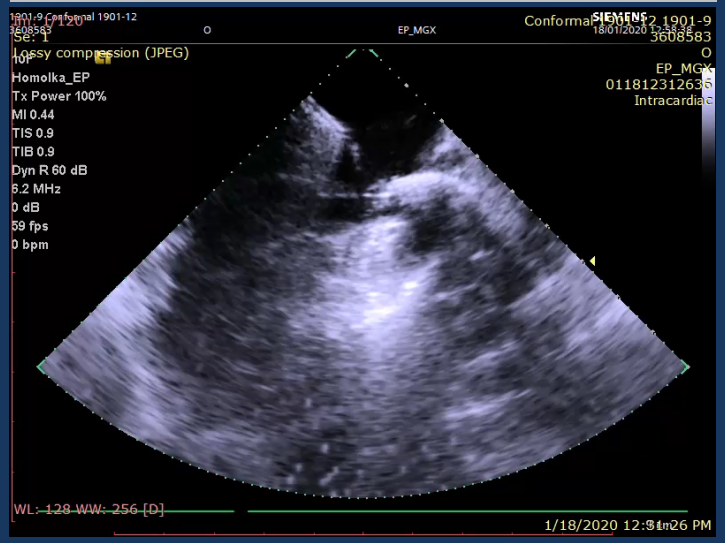
Angio: Baseline



ICE Guided: Deployment



ICE Guided: Tug Test



Patient 1901-09

- 74 y/o F
- Hx of epistaxis (CHA_2DS_2-VASc 4)
- TEE evaluation: 24 x 27 mm
- Implant size: regular

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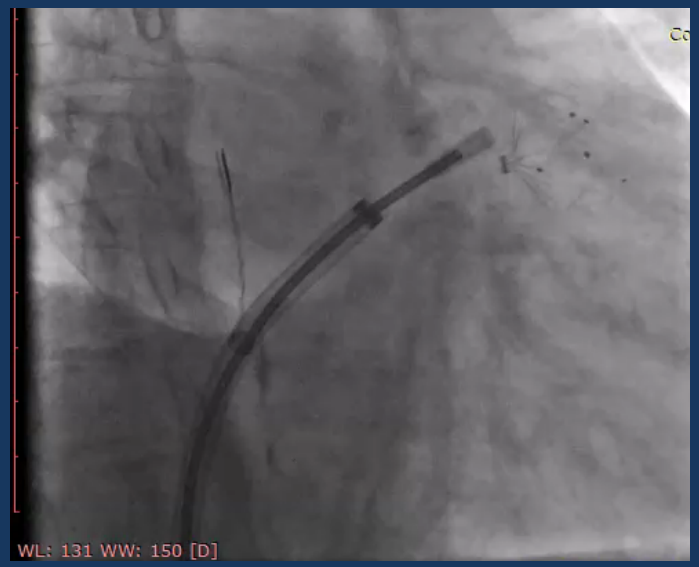
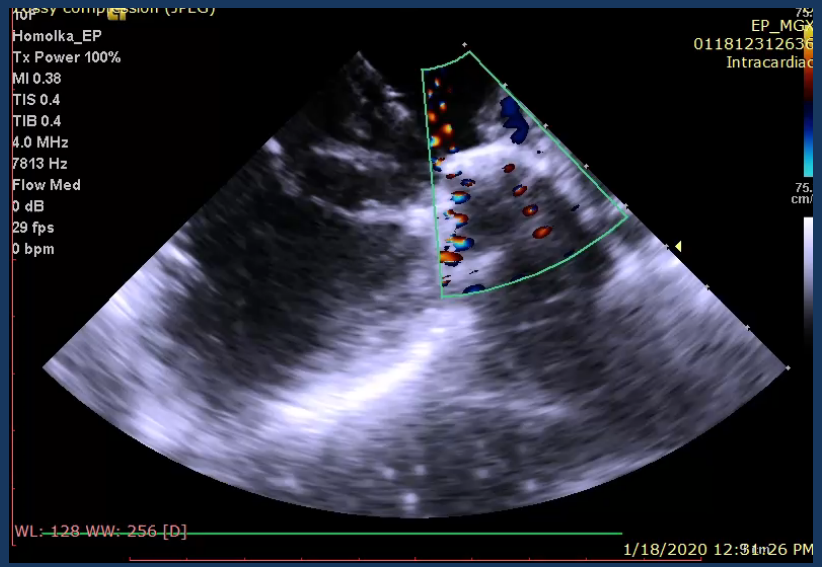
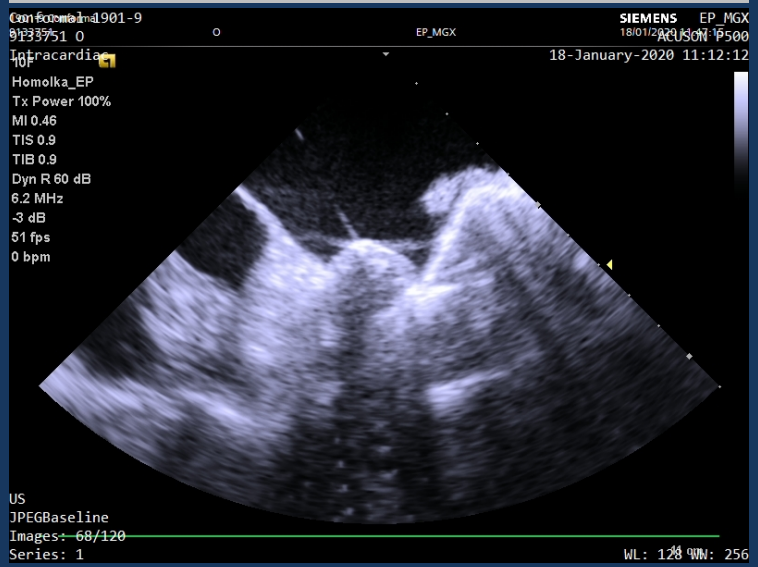
Angio: Position & Leak Assessment



ICE Guided: Leak Assessment



ICE Guided: Position Assessment



Patient 1901-09

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Conformal Prague-EFS ICE Study

Patient Demographics

Enrolled Patients	15
Successful implants	15 (100%)
Age	71.3 ± 10.8 yrs
Gender (Male/Female)	5 / 10 (67% / 33%)
CHA_2DS_2-VASc	4.1 ± 1.7
HAS-BLED	3.4 ± 1.4

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Results

Device procedural complications	0
LAA diameters (mean / range)	11 – 28 mm
Conformal sizes used (n)	12 regular, 2 large
Placement time (min)	55.1 ± 20.6 min
Contrast (cc)	41.5 ± 14.5
FU (45D, 6M, 1Y) as of 23-Sept-2020	15, 15, 0
Leaks (45D)	1 @ 1 mm, 1 @ 2 mm
Device related thrombus (45D)	1

As of 25Sept20

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Conclusions

The Conformal LAAC device using an ICE / Conscious Sedation Protocol:

- Is feasible
- 2 sizes address a large range of LAA anatomies
- Ability to assess seal without TEE

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Conformal Next Steps

ICE Protocol Additional 5-10 patients	▪ Evaluate Gen 2 Delivery System ▪ Validate pivotal device delivery protocol ▪ Complete in Q1 2021
Pivotal Trial (FDA IDE)	▪ RCT: Conformal LAAC *vs* Watchman-FLX ▪ 1:1, n ~ 1,400 ▪ Primary endpoint: 1-year clinical events, seal ▪ Secondary endpoint: 18-month stroke & systemic embolism ▪ First patient: Q2 2021

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Thank you

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