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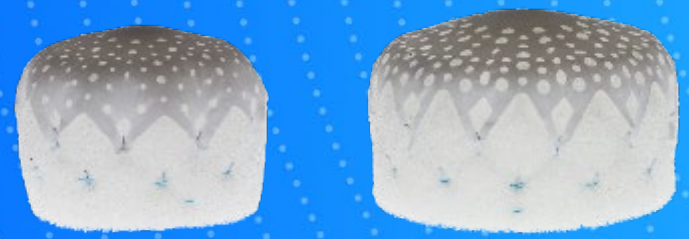
THE SHAPE OF STROKE PREVENTION

CONFORM Pivotal Trial
Pre-Procedure Review Template



V5.0 05MAR2025

Site and Subject Information

SITE TO COMPLETE THE INFORMATION ON THIS PAGE

		Mark “X” for which cohort this subject is intended	
Review Date	**Subject ID**	**Roll – In Cohort**	**Randomized Cohort**
	21000-000		X

Site Name	Example Medical Center
Name of Implanting Physician	Dr. Jane Doe
Name of Procedural Imager	Dr. John Smith
Number of CONFORM procedures to date	1

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Subject Demographics 21000-000

SITE TO COMPLETE THE INFORMATION ON THIS PAGE

Age/Gender	75/Female
Brief Medical History	Persistent Afib, HTN, Hyperlipidemia, DM1
What type of Afib? (permanent/persistent/paryoxysmal)	Paryoxysmal
CHA2DS2VASc (CHF-1, HTN-1, >65-1, DM-1, Stroke-2, Vasc Dz-1, >75-1, F-1)	3
What is the rational to seek non-pharmacologic alternative to OAC?	Bleed risk, Anemia

Echo review - **SITE** to Complete for evaluated criteria

Subject 21000-000

EF per screening imaging	**60%**	
	Mark “x” for response	
	Yes	**No**
Intracardiac thrombus		X
ASD requiring closure		X
High Risk PFO: Atrial septal aneurysm (excursion or length >15mm) / Large shunt (early within 3 beats or substantial passage of bubbles >20)		X
Moderate or severe mitral stenosis (area < 1.5cm^2)		X
Complex atheroma with mobile plaque in aorta (descending/Arch)		X
Evidence of cardiac tumor		X
Inadequate LAA depth		X
Unfavorable LAA configuration		X
LAA size not within device sizing specifications (Control or CLAAS)		X
Circumferential Pericardial Effusion Present?		X
If yes, is the Pericardial effusion >10mm		

Baseline TEE performed at the time of procedure in conjunction with Field Clinical Specialist review will provide final confirmation

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Echo review – Subject 21000-000

NOTE: A Conformal Field Clinical Specialist or Imaging Manager will embed the specified Echo or CT images into this slide deck.

0°

45°

Diameter Min:
Diameter Max:
Diameter Mean:
Functional Depth ≥10mm:

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Echo review – Subject 21000-000

NOTE: A Conformal Field Clinical Specialist of Imaging Manager will embed the specified Echo images into this slide deck.

90°

135°

Diameter Min: 19 mm
Diameter Max: 26 mm
Diameter Mean: 22.5 mm
Functional Depth ≥10mm: 15 mm

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CT review – Subject 21000-000

NOTE: A Conformal Field Clinical Specialist of Imaging Manager will embed the specified CT images into this slide deck.

- LAA Dimensions

Volume Render Image

En Face Ostial Min/Max/Mean

2D Orthogonal Width & Depth

2D Orthogonal Width & Depth

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Suitability for Roll-In
SPONSOR Will Complete
Subject 21000-000

NOTE: Conformal will complete this slide for Roll in Subjects. Please do not fill out this slide. See below for example of sponsor populated slide.

- Executive Committee Member(s)
  - Drs. Aaron Kaplan & Devi Nair
    - ❑ Not Required
- Sponsor Representative(s)
  - Clinical Site Manager: Aly Dechert
  - Field Clinical Specialist: David Houck
- Site Presenter/Implanting physician
  - Dr. Jane Doe

- Roll-In Suitability
  - ☒ Suitable
  - ❑ Not Suitable
    - ❑ Does not meet sizing criteria
    - ❑ Not anatomically suitable
    - ❑ Other (specify)
- Has site completed all required reviews
  - ❑ Yes
  - ☒ No
    - Number of Reviews Remaining: 3
- Additional Notes: Diameter and depth measurements via TEE in 0, 45, 90, and 135 views on day of procedure are required to confirm device size selection and LAA measurements permit CLAAS and commercial devices, per IFU sizing criteria.

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Suitability for Randomization
SPONSOR Will Complete
Subject 21000-000

NOTE: Conformal will complete this slide for Randomized Subjects. Please do not fill out this slide. See below for example of sponsor populated slide.

- Executive Committee Member(s)
  - Drs. Aaron Kaplan & Devi Nair
    - ❑ Not Required
- Sponsor Representative(s)
  - Clinical Site Manager: Aly Dechert
  - Field Clinical Specialist: David Houck
- Site Presenter/Implanting physician
  - Dr. Jane Doe

- Randomization Suitability
  - ☒ Suitable
  - ❑ Not Suitable
    - ❑ Does not meet sizing criteria
    - ❑ Not anatomically suitable
    - ❑ Other (specify)

- Has site completed all required reviews
  - ❑ Yes
  - ☒ No
    - Number of Reviews Remaining: 3

- Additional Notes: Diameter and depth measurements via TEE in 0, 45, 90, and 135 views on day of procedure are required to confirm device size selection and LAA measurements permit CLAAS and commercial devices, per IFU sizing criteria.

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Sizing Criteria

ASP: Release Criteria

1 Anchor

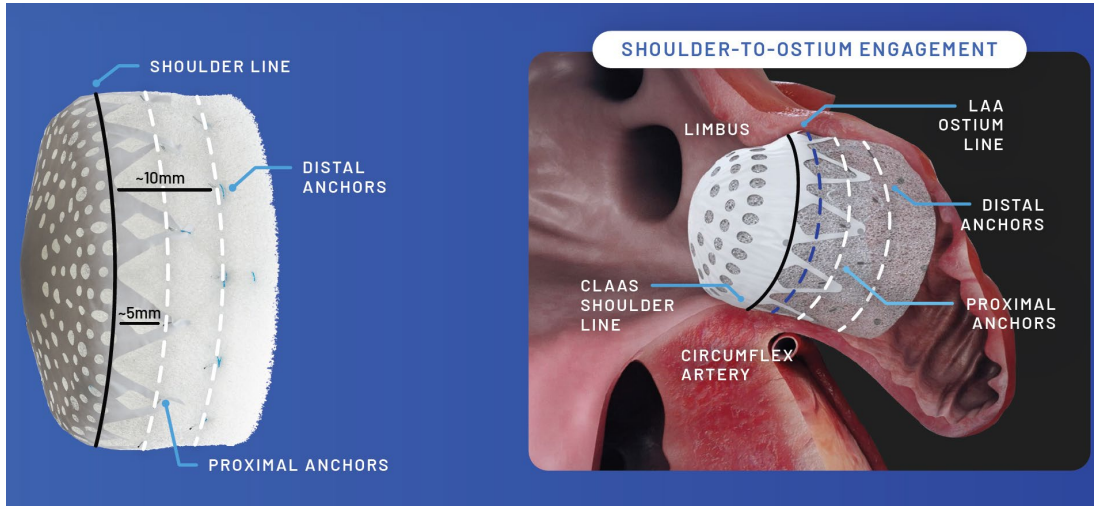
- Observe coincident tissue/implant movement during Tug Test
- Repeat if implant movement is observed from the deployed position

2 Seal

- Target < 3mm leak in all FOUR ultrasound views (0°, 45°, 90°, 135°)

3 Position

- CLAAS Shoulder at or slightly proximal to LAA ostium*
- CLAAS position evaluated in all FOUR ultrasound views (0°, 45°, 90°, 135°)
- Target deployment is for the Shoulder Line to be < 5mm proximal to the LAA ostium and not to exceed 8mm



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CLAAS® AcuFORM Sizing Criteria

A baseline TEE should be performed to verify that a patient's anatomy is appropriate for the CLAAS to be implanted. Perform baseline analysis to confirm appropriate LAA anatomy and absence of LAA thrombus.

1. Assess the following through multiple imaging planes (e.g., 0°, 45°, 90°, 135°).
    a. LAA size/shape, number of lobes in the LAA and location of lobes relative to ostium
    b. Confirm the absence of thrombus (use Color Doppler and echo contrast as necessary)
2. Record the largest (D_{max}) and smallest (D_{min}) LAA ostium diameters and LAA depth (0°, 45°, 90° and 135° sweep).
3. Identify if the CLAAS Implant will fit based on Table 1.

Table 1: CLAAS Implant sizing

CLAAS Size	Mean LAA Ostium Diameter (D_{min} + D_{max}) / 2	LAA Ostium Diameter Ranges (Dmin & Dmax must be within range)	Minimum Landing Zone (Depth)
Regular	≤ 25 mm	10 – 33 mm	10 mm
Large	≤ 32 mm	20 – 40 mm	10 mm

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Watchman FLX IFU Sizing Criteria

7. Confirm LAA size and select appropriate WATCHMAN FLX Device. Transesophageal echocardiography (TEE) and fluoroscopy were used in most WATCHMAN clinical trials for selection of device size and implant guidance. There is limited evidence to support the use of intracardiac echocardiography (ICE) and fluoroscopy to guide LAAC implantation.

   A. Perform the following through multiple imaging views:
      - Measure the LAA length and width at the ostium.
      - Assess LAA size/shape, number of lobes, and location of lobes relative to the ostium.
      - Confirm the absence of thrombus.

Note: TEE imaging recommendations: Measure the LAA ostium at approximately these angles as anatomy permits:
- at 0° measure from coronary artery marker to a point approximately 2 cm from tip of the "limbus."
- at 45° measure from top of the mitral valve annulus to a point approximately 2 cm from tip of the "limbus."
- at 90° measure from top of the mitral valve annulus to a point approximately 2 cm from tip of the "limbus."
- at 135° measure from top of the mitral valve annulus to a point approximately 2 cm from tip of the "limbus."

   B. Choose a Closure Device based on maximum LAA ostium width recorded. Use **Table 45** as a guide. The LAA depth should be approximately half the labeled implant diameter or longer.

Note: LAA anatomy should accommodate a single Closure Device as described in **Table 45**.

Table 45. WATCHMAN FLX Device Selection

Max LAA Ostium Width and/or Deployed Closure Device Diameter (mm)	Closure Device Size (mm)
14.0 – 18.0	20
16.8 – 21.6	24
18.9 – 24.3	27
21.7 – 27.9	31
24.5 – 31.5	35

Note: These values are based on TEE. Other imaging modalities may vary.

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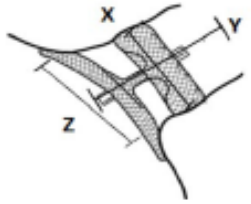
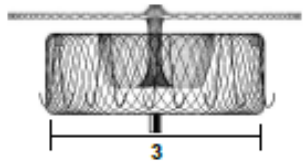
Amulet Sizing Criteria

5. Use angiography, TEE (preferably 3D), or pre-procedural cardiac CT to measure the left atrial appendage, including the depth of the left atrial appendage (shown as Y in Table 2, in Appendix A) and the maximum width of the orifice (shown as Z in Table 2 in Appendix A). Image the left atrial appendage until it is clearly visible.
   - Identify and measure the left atrial appendage at the landing zone (defined as a minimum of 10–12 mm from the orifice) for the device lobe (shown as X in Table 2 in Appendix A: Supplemental Information) to determine the appropriate device size to occlude the left atrial appendage.
   - Consider using two imaging modalities to inform sizing. Use the maximum landing zone measurement if using 2D TEE or angiography and mean landing zone measurement if using 3D TEE or pre-procedural CT. When choosing between two sizes, consider depth and orifice measurements, confirming the orifice measurement (shown as Z in Table 2 of Appendix A: Supplemental Information) is less than the disc size of the selected device and there is sufficient depth. See Table 2 in Appendix A to determine the appropriate device size to occlude the left atrial appendage.

WARNING: Do not implant the device if the measurements of the left atrial appendage do not fall within the sizing chart in Table 2 of Appendix A.

Table 2. Sizing chart





Landing Zone Width X[a]	Distance from Orifice Y	Device Size (Lobe Diameter) 3	Device Order Number
mm	mm	mm	
11.0 - 13.0	≥ 10	16	9-ACP2-007-016
13.0 - 15.0	≥ 10	18	9-ACP2-007-018
15.0 - 17.0	≥ 10	20	9-ACP2-007-020
17.0 - 19.0	≥ 10	22	9-ACP2-007-022
19.0 - 22.0	≥ 12	25	9-ACP2-010-025
22.0 - 25.0	≥ 12	28	9-ACP2-010-028
25.0 - 28.0	≥ 12	31	9-ACP2-010-031
28.0 - 31.0	≥ 12	34	9-ACP2-010-034

a. The landing zone is where the lobe of the device will be placed in the left atrial appendage.

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