conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Inclusion/Exclusion Criteria** ☐ Source ☐ Data Transfer Tool
	Site Number: _____ Subject ID: _____

Have all the inclusion criteria and none of the exclusion criteria, as specified by the protocol, been met for this subject?	☐ Yes ☐ No ☐ N/A – Inclusion and Exclusion Criteria not assessed
What primary imaging modality was used to assess Echo Exclusion Criteria?	☐ TTE – Transthoracic echocardiogram ☐ CT ☐ MRI ☐ TEE – Transesophageal echocardiogram ☐ None

Inclusion Criteria

*Potential subjects must meet **ALL** of the following criteria to be eligible for inclusion in the study:*

Inclusion Criteria	Yes	No	N/A – Not assessed
1. Male or nonpregnant female aged ≥ 18 years?	☐	☐	☐
2. Documented non-valvular AF (paroxysmal, persistent, or permanent)?	☐	☐	☐
3. High risk of stroke or systemic embolism, defined as CHA_2DS_2-VASc score of ≥ 3?	☐	☐	☐
4. Has an appropriate rationale to seek a non-pharmacologic alternative to long-term oral anticoagulation?	☐	☐	☐
5. Deemed by the site investigator to be suitable for short term oral anticoagulation therapy but deemed less favorable for long-term oral anticoagulation?	☐	☐	☐
6. Deemed appropriate for LAA closure by the site investigator and a clinician not a part of the procedural team using a shared decision-making process in accordance with standard of care?	☐	☐	☐
7. Able to comply with the protocol-specified medication regimen and follow-up evaluations?	☐	☐	☐
8. The subject (or legally authorized representative, where allowed) has been informed of the nature of the study, agrees to its provisions, and has provided written informed consent approved by the appropriate Institutional Review Board (IRB)/Regional Ethics Board (REB)?	☐	☐	☐

Exclusion Criteria

*Potential subjects will be excluded if **ANY** of the following conditions apply*

Exclusion Criteria	Yes	No	N/A – Not assessed
1. Pregnant or nursing subjects and those who plan pregnancy in the period up to 1 year following index procedure? Female subjects of childbearing potential must have a negative pregnant test (per site standard test) **within 7 days** prior to index procedure	☐	☐	☐
2. Anatomic conditions that would prevent performance of an LAA occlusion procedure (e.g., prior atrial septal defect [ASD] or high-risk patent foramen ovale [PFO], surgical repair or implanted closure device, or obliterated or ligated left atrial appendage)?	☐	☐	☐
3. Atrial fibrillation that is defined by a single occurrence or that is transient or reversible (e.g., secondary thyroid disorders, acute alcohol intoxication, trauma, recent major surgical procedures)?	☐	☐	☐
4. A medical condition (other than atrial fibrillation) that mandates long-term oral anticoagulation (e.g., history of unprovoked deep vein thrombosis or pulmonary embolism, or mechanical heart valve)?	☐	☐	☐
5. History of bleeding diathesis or coagulopathy, or subjects in whom antiplatelet and/or anticoagulant therapy is contraindicated?	☐	☐	☐
6. Documented active infection?	☐	☐	☐
7. Symptomatic carotid artery disease (defined as >50% stenosis with symptoms of ipsilateral transient or visual TIA evidence by amaurosis fugax, ipsilateral hemispheric TIAs or ipsilateral stroke)? If subject has a history of carotid stent or endarterectomy, the subject is eligible if there is <50% stenosis at the site of prior treatment	☐	☐	☐
8. Recent (**within 30 days** of index procedure) or planned (**within 60 days** post-procedure) cardiac or non-cardiac interventional or surgical procedure?	☐	☐	☐
9. Recent (**within 30 days** of index procedure) stroke or transient ischemic attack?	☐	☐	☐
10. Recent (**within 30 days** of index procedure) myocardial infarction?	☐	☐	☐
11. Vascular access precluding delivery of implant with catheter-based system?	☐	☐	☐
12. Severe heart failure (New York Heart Association Class IV)?	☐	☐	☐
13. Prior cardiac transplant, history of mitral valve replacement or transcatheter mitral valve intervention, or any mechanical valve implant?	☐	☐	☐
14. Renal insufficiency, defined as estimated glomerular filtration rate (eGFR) <30 mL/min/1.73m^2 (by the Modification of Diet in Renal Disease equation)?	☐	☐	☐

Exclusion Criteria	Yes	No	N/A – Not assessed
15. Platelet count < 75,000 cells/mm^3 or > 700,000 cells/ mm^3, or white blood cell count < 3,000 cells/ $mm^{3?}$	☐	☐	☐
16. Known allergy, hypersensitivity or contraindication to aspirin, heparin, or device materials (e.g., nickel, titanium) or that would preclude any P2Y12 inhibitor therapy, or the subject has contrast sensitivity that cannot be adequately pre-medicated?	☐	☐	☐
17. Actively enrolled or plans to enroll in a concurrent clinical study in which the active treatment arm may confound the results of this trial?	☐	☐	☐
18. Unable to undergo general anesthesia?	☐	☐	☐
19. Known other medical illness or known history of substance abuse that may cause non-compliance with the protocol or protocol-specified medication regimen, confound the data interpretation, or is associated with a life expectancy of less than 5 years?	☐	☐	☐
20. A condition which precludes adequate transesophageal echocardiographic (TEE) assessment?	☐	☐	☐

Screening Echocardiographic Exclusion Criteria

*This is based on historical imaging (performed within 6 months prior to consent) at Screening. Cardiac CT or TEE can be used to assess all criteria TTE and MRI studies are limited to the confirmed assessment of #3 and #4. Potential subjects will be excluded if **ANY** of the following conditions are known to apply*

Exclusion Criteria	Yes	No	N/A – Not assessed
1. Left atrial appendage cannot accommodate either a commercially available device of the CLAAS device per manufacturer IFU (e.g., the anatomy and sizing must be appropriate for both devices in order to be enrolled in the trial)?	☐	☐	☐
2. Intracardiac thrombus or dense spontaneous echo contrast consistent with thrombus, as visualized by TEE prior to implant?	☐	☐	☐
3. Left ventricular ejection fraction (LVEF) < 30%?	☐	☐	☐
4. Existing circumferential pericardial effusion > 10 mm or symptomatic pericardial effusion, signs, or symptoms of acute or chronic pericarditis, or evidence or tamponade physiology?	☐	☐	☐
5. Atrial septal defect that warrants closure?	☐	☐	☐
6. High risk patent foramen ovale (PFO), defined as an atrial septal aneurysm (exclusion > 15 mm or length > 15 mm) or large shunt (early [within 3 beats] and/or substantial passage of bubbles, e.g., > 20)?	☐	☐	☐
7. Moderate or severe mitral valve stenosis (mitral valve area < 1.5 cm^2)?	☐	☐	☐
8. Complex atheroma with mobile plaque of the descending aorta and/or aortic arch?	☐	☐	☐
9. Evidence of cardiac tumor?	☐	☐	☐

Reminder: *If a significant cardiac event (potentially related to a change in cardiac status, e.g., CHF decompensation) occurs after cardiac imaging is obtained and before randomization takes place- then imaging should be repeated.*

_____ __ __ / __ __ __ / __ __ __ __
Site Personnel Signature **Date (DD/MMM/YYYY)**

_____ __ __ / __ __ __ / __ __ __ __
Investigator Signature **Date (DD/MMM/YYYY)**