Echo Exclusion Criteria

1. Left atrial appendage anatomy which cannot accommodate a commercially available control device or the CLAAS Implant per manufacturer IFU (e.g., the anatomy and sizing must be appropriate for both the investigational (CLAAS) and a commercially available device in order to be enrolled in the trial).
2. Intracardiac thrombus or dense spontaneous echo contrast consistent with thrombus, as visualized by TEE.
3. Left ventricular ejection fraction (LVEF) <30%.
4. Moderate or large pericardial effusion >10mm or symptomatic pericardial effusion, signs or symptoms of acute or chronic pericarditis, or evidence of tamponade physiology.
5. Atrial septal defect that warrants closure.
6. High risk patent foramen ovale (PFO), defined as an atrial septal aneurysm (excursion >15mm or length >15mm) 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 <1.5cm^2).
8. Complex atheroma with mobile plaque of the descending aorta and/or aortic arch.
9. Evidence of cardiac tumor.

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CONFORM
PIVOTAL TRIAL

PATIENT INCLUSION & EXCLUSION CRITERIA
Protocol Rev R.

Inclusion Criteria

1. Male or non-pregnant female aged ≥18 years.
2. Documented non-valvular AF (paroxysmal, persistent, or permanent).
3. High risk of stroke or systemic embolism, defined as CHA2DS2-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 therapy.
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 patient (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)/Ethics Committee (EC).

CAUTION: Investigational Device. The CLAAS® AcuFORM™ System is limited by federal law (United States) to investigational use. Exclusively for clinical investigation outside the United States. Not approved for commercial use.

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Exclusion Criteria

1. Pregnant or nursing patients and those who plan pregnancy in the period up to one year following the index procedure. Female patients of childbearing potential must have a negative pregnancy 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., atrial septal defect (ASD) requiring closure, high-risk patent foramen ovale (PFO) requiring closure, a highly mobile inter-atrial septal aneurysm precluding a safe TSP, presence of a PFO/ASD closure device, history of surgical ASD repair or history of surgical LAAO closure).
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 prosthetic mechanical heart valve).
5. History of bleeding diathesis or coagulopathy, or patients in whom antiplatelet and/or anticoagulant therapy is contraindicated.
6. Documented active systemic infection.
7. Symptomatic carotid artery disease (defined as >50% stenosis with symptoms of ipsilateral transient or visual TIA evidenced 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 noted at the site of prior treatment.
8. Recent (**within 30 days** of index procedure) or planned (**within 60 days** post-procedure) cardiac or major 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 prosthetic mechanical valve implant.
14. Renal insufficiency, defined as estimated glomerular filtration rate (eGFR) <30mL/min/1.73 m2 (by the Modification of Diet in Renal Disease equation).
15. Platelet count <75,000 cells/mm3 or >700,000 cells/mm3, or white blood cell count <3,000 cells/mm3.
16. Known allergy, hypersensitivity or contraindication to aspirin, heparin, or that would preclude any P2Y12 inhibitor therapy, or to device materials (e.g., nickel, titanium), 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.