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

Echocardiographic Exclusion Criteria
REMINDER: Procedural ultrasound imaging will be performed by a qualified physician who is *not* the implanting physician.
*Potential subjects will be excluded if **ANY** of the following conditions apply*

Exclusion Criteria	Yes	No
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?	☐	☐

If utilizing as source (no other source exists)- form should be signed by device implanter or echocardiographer present at implant.

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

* If any of the listed exclusions are marked as YES, the subject shall be considered a Screen Failure and will be followed for 45 days to evaluate safety.

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