conformal™ The Shape of Stroke Prevention	**Title:**
	MOP 05 – Study Schema Table

Protocol Rev M

	Screening	Procedure[0]	Pre-Discharge	7-Day	45-Day	6 Month (180 days)	12 Month (365 days)	18 Month (545 days)	2, 3, 4, 5 Year (730, 1095, 1460, 1825 days)	Stroke/SE Assessment[1]
		Day 0		+2 Days	±7 Days	±30 Days	±30 Days	±30 Days	±60 Days	+14 Days
	Clinic Visit			Telehealth[2]	Clinic Visit/ Telehealth[2]	Telehealth[2]	Clinic Visit/ Telehealth[2]	Clinic Visit	Telehealth[2]	
Informed Consent	X									
Medical and Surgical History	X									X
Physical Exam/Assessment	X									X
Vital Signs	X									
CHA_2DS_2-VASc	X									
HAS-BLED	X									
Serum Creatinine or GFR/eGFR	X[3]									
CBC, Platelet count and Hgb/Hct	X[3]	X[4]								
ECG 12 Lead	X[5]									
Pregnancy Test	X[6]									
Neuro Assessment	X[7]		X					X		X
QVSFS	X[8]			X	X	X	X	X	X	X
Cardiac CT	X[9]				X[11]		X[11]			
TTE	X[9]		X[10]							
TEE	X[9]	X			X[12]		X[12]			X
Brain Imaging	X[13]									X[14]
AE Assessment	X	X	X	X	X	X	X	X	X	X
Medication Review[15]	X	X	X	X	X	X	X	X	X	X
INR[16]	X	X								
Randomization	X[17]									
LAA Measurements		X								

TABLE FOOTNOTES Protocol Rev M

[0] Procedure must occur within 14 days from the date of randomization.

[1] In the event of a suspected stroke or systemic embolism, a clinical assessment is required within 14 days after the site becomes aware of the event. If the patient is unable to travel due to hospitalization or disability, chart review can be performed in lieu of clinic visit.

[2] Tele-Health Visit: Clinical evaluation can be performed via phone call, video link or clinic visit.

[3] May be performed as part of standard of care up to 60 days prior to consent.

[4] Performed within 48 hours of index procedure.

[5] Performed within 30 days prior to the index procedure may be used as the baseline ECG, provided there have been no signs or symptoms of myocardial ischemia between the time of the ECG and the screening assessment (in which case the ECG should be performed within 24 hours prior to the index procedure).

[6] Required for females of childbearing potential within 7 days of index procedure (by site standard, either serum or urine).

[7] Neuro Assessment to include National Institute of Health Stroke Scale (NIHSS) and Modified Rankin Scale for Neurologic Disability (MRS) within 30 days of index procedure. The pre-discharge stroke assessment must be done after the effects of anesthesia.

[8] QVSFS: Questionnaire for Verifying Stroke-Free Status within 30 days of index procedure.

[9] **Screening imaging (TEE or CT) must be performed prior to randomization.** Imaging is required to assess the anatomic screening criteria. Cardiac CT or TEE can be used to assess all Echocardiographic Eligibility Criteria. TTE and MRI studies are limited to the assessment of Left ventricular ejection fraction and for detection of pericardial effusions. TTE and MRI cannot be used to assess other Echocardiographic Eligibility Criteria.

[10] Implanted subjects only (does not include patients who did not receive a LAAO device). TTE is required to surveil for pericardial effusion. The study must be performed at a minimum of 4 hours from the end of the procedure (removal of the access sheath).

[11] Cardiac CT may be used in lieu of TEE to screen for end point findings, e.g., DRT or >3mm peri-device Leak.

- If a Device Related Thrombus is detected, a TEE is required to confirm the finding as soon as possible (recommended assessment within 2 weeks; at latest, 4-6 weeks from date of original study or at the patient's next follow up visit, whichever is first).
- If a non-trivial peri-device leak is noted on CT, a TEE is required to confirm the finding, as soon as possible (ideally within 2 weeks; at latest, 4-6 weeks from date of original study or at the patient's next follow up visit, whichever is first).

  Note: A non-trivial peri-device leak found on CT is one in which the site investigator determination indicates a likely finding of leak >3mm if measured by TEE.
- If a Pericardial Effusion measuring >10mm is detected on Cardiac CT, TTE evaluation is suggested for quantification.

[12] If TEE demonstrates a pericardial effusion (measuring >10 mm, a TTE is required.

[13] Brain Imaging: For subjects with documented history of TIA/Stroke in the 24-month period prior to enrollment, the most recent brain imaging (CT/MRI) report is required at baseline. If there is no available imaging report or there has been a suspected neuro event, brain imaging may be requested by the Sponsor as a baseline reference.

[14] Brain Imaging is ONLY required for patients with Systemic Embolism (SE) if there are new findings suggestive of TIA/Stroke.

[15] Medication assessment data collection includes the use of antiplatelet, anticoagulation and prophylactic antibiotic medication only.

[16] INR levels required only for patients taking Warfarin, or in accordance with standard of care.

[17] **Randomization only after all clinical assessments and eligibility criteria are confirmed** and shall be performed within 90 days of informed consent.