NCDR® Data Collection Form v1.1 LAAO Registry™

A. Demographics

Last Name[2000]:	**First Name**[2010]:	**Middle Name**[2020]:
SSN[2030]: - - ☐ SSN N/A[2031]	**Patient ID**[2040]: *(auto)*	**Other ID**[2045]:
Birth Date[2050]: mm / dd / yyyy	**Sex**[2060]: O Male O Female	**Patient Zip Code**[2065]: ☐ Zip Code N/A[2066]

Race: (check all that apply)
☐ White[2070] ☐ Black/African American[2071] ☐ American Indian/Alaskan Native[2073]
☐ Asian[2072] → **If** Yes, ☐ Asian Indian[2080] ☐ Chinese[2081] ☐ Filipino[2082] ☐ Japanese[2083] ☐ Korean[2084] ☐ Vietnamese[2085] ☐ Other[2086]
☐ Native Hawaiian/Pacific Islander[2074] → **If** Yes, ☐ Native Hawaiian[2090] ☐ Guamanian or Chamorro[2091] ☐ Samoan[2092] ☐ Other Island[2093]

Hispanic or Latino Ethnicity[2076]: O No O Yes → **If** Yes, **Ethnicity Type:** (check all that apply)
☐ Mexican, Mexican-American, Chicano[2100] ☐ Puerto Rican[2101] ☐ Cuban[2102] ☐ Other Hispanic, Latino or Spanish Origin[2103]

B. Episode of Care (Admission)

Arrival Date[3000]: mm / dd / yyyy

Health Insurance[3005]: O No O Yes

→ **If** Yes, **Payment Source**[3010]: (Select all that apply)
☐ Private Health Insurance ☐ Medicare ☐ Medicaid ☐ Military Health Care
☐ State-Specific Plan (non-Medicaid) ☐ Indian Health Service ☐ Non-US Insurance

HIC #[3015]:

Research Study[3020]: O No O Yes → **If** Yes, **Study Name**[3025], **Patient ID**[3030]: _____, _____ ☐ **Patient Restriction**[3035]

Admitted for LAA Occlusion Intervention [3045]: O No O Yes

C. History and Risk Factors (Prior to First Procedure)

Specific to CHA_2DS_2-VASc risk scores[1]

CHA_2DS_2-VASc Congestive Heart Failure[4005]: O No O Yes
→ **If** Yes, **NYHA Functional Classification**[4010]: O Class I O Class II O Class III O Class IV

CHA_2DS_2-VASc LV Dysfunction[4015]:	O No	O Yes	**CHA_2DS_2-VASc Thromboembolic Event**[4040]:	O No	O Yes
CHA_2DS_2-VASc Hypertension[4020]:	O No	O Yes	**CHA_2DS_2-VASc Vascular Disease**[4045]:	O No	O Yes
CHA_2DS_2-VASc Diabetes Mellitus[4025]:	O No	O Yes	→ **If** Yes, **Vascular Disease Type**[4050]: (Select all that apply)		
CHA_2DS_2-VASc Stroke[4030]:	O No	O Yes	☐ Prior MI ☐ PAD ☐ Known Aortic Plaque		
CHA_2DS_2-VASc TIA[4035]:	O No	O Yes			

Specific to HAS-BLED risk scores[1]

HAS-BLED Hypertension (Uncontrolled)[4055]:	O No	O Yes	**HAS-BLED Bleeding**[4095]:	O No	O Yes
HAS-BLED Abnormal Renal Function[4060]:	O No	O Yes	**HAS-BLED Labile INR**[4100]:	O No	O Yes
HAS-BLED Abnormal Liver Function[4065]:	O No	O Yes	**HAS-BLED Alcohol**[4105]:	O No	O Yes
HAS-BLED Stroke[4070]:	O No	O Yes	**HAS-BLED Drugs - Antiplatelet**[4110]:	O No	O Yes
→**If** Yes, **Hemorrhagic**[4075]:	O No	O Yes	**HAS-BLED Drugs - NSAIDS**[4115]:	O No	O Yes
→**If** Yes, **Ischemic**[4080]:	O No	O Yes			
→**If** Yes, **Undetermined**[4085]:	O No	O Yes			

[1] CHA_2DS_2-VASc and HAS-BLED Risk Scores are used with the permission of Gregory YH Lip MD, FRCP (London, Edinburgh, Glasgow), DFM, FACC, FESC

Additional Stroke and Bleeding Risk Factors (non-Risk Score related)

Increased Risk of Falls[4120]: O No O Yes

Clinically Relevant Bleeding Event[4125]: O No O Yes

→**If** Yes, **Bleeding Event Type**[4130]: (Select all that apply) ☐ Intracranial ☐ Epistaxis ☐ Gastrointestinal ☐ Other

→**If** Yes, **Genetic Coagulopathy**[4135]: O No O Yes

→**If** Yes, **Concurrent Anticoagulant Therapy**[4140]: O No O Yes

History – Rhythm History

Atrial Fibrillation Classification[4400]:

O Paroxysmal *(terminating spontaneously w/in 7 days)* O Long standing persistent *(>1 year)*
O Persistent *(>7 days)* O Permanent

Valvular Atrial Fibrillation[4380]: O No O Yes

→ **If** Yes**, Hx of Rheumatic Valve Disease**[4381]: O No O Yes

→ **If** Yes**, Hx of Mitral Valve Replacement**[4385]: O No O Yes

→ **If** Yes, **Mechanical Valve in Mitral Position**[4390]: O No O Yes

→ **If** Yes**, Hx of Mitral Valve Repair**[4395]: O No O Yes

Attempt at Atrial Fibrillation Termination[4410]: O No O Yes

→ **If** Yes**, Pharmacologic Cardioversion**[4415]: O No O Yes

→ **If** Yes**, DC Cardioversion**[4420]: O No O Yes

→ **If** Yes**, Catheter Ablation**[4425]: O No O Yes

→ **If** Yes, **Date of Most Recent**[4430]: mm / dd / yyyy

→ **If** Yes**, Prior Ablation Strategy(s)**[4435]: _____, _____, _____, _____

→ **If** Yes**, Surgical Ablation**[4440]: O No O Yes

→ **If** Yes, **Date of Most Recent**[4445]: mm / dd / yyyy

Atrial Flutter[4450]: O No O Yes

→ **If** Yes, **Atrial Flutter Classification**[4455]: O Typical/Cavotricuspid Isthmus (CTI) Dependent O Atypical

→ **If** Yes, **Attempt at Atrial Flutter Termination**[4460]: O No O Yes

→ **If** Yes**, Pharmacologic Cardioversion**[4465]: O No O Yes

→ **If** Yes**, DC Cardioversion**[4470]: O No O Yes

→ **If** Yes**, Catheter Ablation**[4475]: O No O Yes

→ **If** Yes, **Date of Most Recent**[4480]: mm / dd / yyyy

History – Interventions

Cardiac Structural Intervention[4590]: O No O Yes

→ **If** Yes, **Cardiac Structural Intervention Type**[4595]: (Select all that apply)

☐ Aortic Balloon Valvuloplasty
☐ AV Repair – surgical
☐ MV Replacement – surgical
☐ Mitral Transcatheter – valve-in-valve
☐ Pulmonic Replacement
☐ Tricuspid Repair
☐ Transcatheter Aortic Valve Replacement (TAVR)
☐ Mitral Balloon Valvuloplasty
☐ MV Repair – surgical
☐ ASD Closure
☐ Pulmonic Repair
☐ AV Replacement – surgical
☐ Transcatheter Mitral Valve Repair (TMVR)
☐ Mitral Annuloplasty Ring – surgical
☐ PFO Closure
☐ Tricuspid Replacement

Left Atrial Appendage (LAA) Intervention[4600]: O No O Yes

→ **If** Yes, **Left Atrial Appendage (LAA) Intervention Type**[4605]: (Select all that apply)
☐ Epicardial Ligation
☐ Surgical Amputation
☐ Surgical Ligation
☐ Percutaneous Occlusion
☐ Surgical Closure Device
☐ Surgical Stapling

Additional History and Risk Factors

Cardiomyopathy (CM)[4565]: O No O Yes

→ **If** Yes**, CM Type**[4570]: (Select all that apply) ☐ Non-Ischemic ☐ Ischemic ☐ Restrictive ☐ Hypertrophic ☐ Other

Chronic Lung Disease[4575]: O No O Yes	**Sleep Apnea**[4580]: O No O Yes
Coronary Artery Disease[4285]: O No O Yes	→ **If** Yes**, Rx Followed**[4585]: O No O Yes

Epicardial Access Assessment

Epicardial Approach Considered[4815]:	O No	O Yes	→ **If** Yes, (complete the following)		
Cardiac Surgery[4820]:	O No	O Yes	**Thoracic Radiation Therapy**[4840]:	O No	O Yes
Pericarditis[4825]:	O No	O Yes	**Pectus Excavatum**[4845]:	O No	O Yes
Epicardial Access[4830]:	O No	O Yes	**Epigastric Surgery**[4850]:	O No	O Yes
Autoimmune Disease (any)[4835]:	O No	O Yes	**Hepatomegaly**[4855]:	O No	O Yes
→ **If** Yes, **Lupus**[4836]:	O No	O Yes	**Hiatal Hernia**[4860]:	O No	O Yes

D. Diagnostic Studies

Atrial Rhythm[5100]: (Select all that apply) ☐ Sinus ☐ AFib ☐ Atrial tach ☐ Atrial flutter ☐ Sinus arrest ☐ Atrial paced ☐ Not Documented

LVEF Assessed[5110]: O No O Yes → **If** Yes, **LVEF**[5115]: _____ %

Transthoracic Echo (TTE) Performed[5120]: O No O Yes → **If** Yes, **Date of TTE**[5125]: mm / dd / yyyy

Baseline Imaging Performed[5170]: O No O Yes

→ **If** Yes, **CT Performed**[5175]: O No O Yes → **If** Yes, **Date of CT**[5180]: mm / dd / yyyy

→ **If** Yes, **MRI Performed**[5185]: O No O Yes → **If** Yes, **Date of MRI**[5190]: mm / dd / yyyy

E. Physical Exam and Labs

Height[6000]: _____ cm	**PT**[6040]: _____ sec	☐ Not Drawn[6041]
Weight[6005]: _____ kg	**INR**[6045]: _____	☐ Not Drawn[6046]
Pulse[6010]: _____ bpm	**Creatinine**[6050]: _____ mg/dL	☐ Not Drawn[6051]
Blood Pressure[6015/6020]: _____/_____ mmHg	**Albumin**[6075]: _____ g/dL	☐ Not Drawn[6076]
Hemoglobin[6030]: _____ g/dL ☐ Not Drawn[6031]	**Platelet Count**[6080]: _____ µL	☐ Not Drawn[6081]

Modified Rankin Scale (mRS)[6085]:
O 0: No symptoms at all
O 1: No significant disability despite symptoms
O 2: Slight disability
O 3: Moderate disability
O 4: Moderately severe disability
O 5: Severe disability
☐ Not Administered[6086]

F. Pre-Procedure Medications

Medication[6985]		Pre-Proc Medication Administered[6990]			
		Past	Current	Held	Never
Antiplatelet	Aggrenox	O	O	O	O
	Aspirin (81 mg)	O	O	O	O
	Aspirin (325 mg)	O	O	O	O
	Durlaza	O	O	O	O
	Vorapaxar	O	O	O	O
P2Y12 Inhibitor	Clopidogrel	O	O	O	O
	Prasugrel	O	O	O	O
	Ticlopidine	O	O	O	O
	Ticagrelor	O	O	O	O
Anticoagulant	Warfarin	O	O	O	O
Non-vitamin K dependent oral anticoagulant	Apixaban	O	O	O	O
	Dabigatran	O	O	O	O
	Rivaroxaban	O	O	O	O
	Edoxaban	O	O	O	O
Bridging Therapy	Unfractionated Heparin	O	O	O	O
	Fondaparinux	O	O	O	O
	Low Molecular Wt Heparin	O	O	O	O
	Heparin Derivative	O	O	O	O

G. Procedure Information

Procedure Diagnostics

Transesophageal Echo (TEE) Performed[5156]: O No O Yes → **If** Yes, **Date of TEE**[5157]: mm / dd / yyyy

→ **If** Yes, **Atrial Thrombus Detected**[5158]: O No O Yes

LAA Orifice Maximal Width[5166]: _____ mm

Procedure

Procedure Start Date/Time[7001,7002]: mm/dd/yyyy / hh:mm | **Procedure Stop Date/Time**[7006,7007]: mm/dd/yyyy / hh:mm

Operator Name[7100,7105,7110]: | **Operator NPI**[7115]:

Procedure Location[7030]: O OR O Hybrid OR O Cath Lab O Hybrid Cath Lab O EP Lab

Sedation[7130]: O Minimal Sedation/Anxiolysis O Deep Sedation/Analgesia
O Moderate Sedation/Analgesia (Conscious Sedation) O General Anesthesia

Indication for LAA Occlusion[7035]: (Select all that apply)

□ Increased thromboembolic stroke risk
□ History of major bleed
□ High fall risk
□ Labile INR
□ Patient preference
□ Non-compliance with anticoagulation therapy

Procedure Canceled[7040]: O No O Yes

→**If** Yes, **Reason**[7041]: (Select all that apply)

□ Anatomy not conducive for implant
□ Catheterization challenge
□ Thrombus detected
□ Appendage too large (for device implant)
□ Decompensation in patient condition
□ Unanticipated patient condition
□ Appendage too small (for device implant)
□ Epicardial access issue
□ Patient/Family choice

List all Devices in Chronological Order

Access System[7270]		Device[7275]		UDI[7280]	LAA Isolation Approach[7285]	Outcome of Device[7290]
1		1		(future)	O Epicardial O Percutaneous	O Deployed, released O Deployed, not released O Not Deployed O Device retrieved
		2		(future)	O Epicardial O Percutaneous	O Deployed, released O Deployed, not released O Not Deployed O Device retrieved
		3		(future)	O Epicardial O Percutaneous	O Deployed, released O Deployed, not released O Not Deployed O Device retrieved
2		1		(future)	O Epicardial O Percutaneous	O Deployed, released O Deployed, not released O Not Deployed O Device retrieved
		2		(future)	O Epicardial O Percutaneous	O Deployed, released O Deployed, not released O Not Deployed O Device retrieved
		3		(future)	O Epicardial O Percutaneous	O Deployed, released O Deployed, not released O Not Deployed O Device retrieved
3		1		(future)	O Epicardial O Percutaneous	O Deployed, released O Deployed, not released O Not Deployed O Device retrieved
		2		(future)	O Epicardial O Percutaneous	O Deployed, released O Deployed, not released O Not Deployed O Device retrieved
		3		(future)	O Epicardial O Percutaneous	O Deployed, released O Deployed, not released O Not Deployed O Device retrieved

Procedure Aborted[7295]: O No O Yes

→**If** Yes, **Reason**[7296]: (Select all that apply)

□ Anatomy not conducive for implant
□ Catheterization challenge
□ Device retrieval
□ Open heart device retrieval
□ Patient/Family choice
□ Appendage too large (for device implant)
□ Decompensation in patient condition
□ Device release criteria not met
□ Thrombus developed during procedure
□ Appendage too small (for device implant)
□ Device related
□ Epicardial access issue
□ Unanticipated patient condition

Conversion to Open Heart Surgery[7300]: O No O Yes

→**If** Yes, **Reason**[7301]: O Complication O Device Retrieval O Unfavorable anatomy
O Medical decision for open ligation of appendage

Device Margin Residual Leak[7305]: _____ mm □ Not Assessed[7306]

Guidance Method(s)[7200]: _____, _____, _____, _____

Concomitant Procedure(s) Performed[7310]: O No O Yes →**If** Yes, **Concomitant Procedure Type**[7315]: (Select all that apply)

□ AFib Ablation
□ ASD Closure Congenital
□ ICD
□ ASD Closure Iatrogenic
□ PCI
□ TAVR
□ PFO Closure Congenital
□ TMVR

Radiation Exposure

Cumulative Air Kerma[7210,7211]**:** _____ O mGy O Gy **Contrast Volume**[7215]**:** _____ mL

Dose Area Product[7220,7221]**:** _____ O Gy-cm^2 O dGy-cm^2 O cGy-cm^2 O mGy-cm^2 O µGy-M^2

Intraprocedure Anticoagulation Strategy

Intraprocedure Anticoagulation[7225]**:** O No O Yes

→ **If** Yes, **Uninterrupted Warfarin Therapy**[7230]**:** O No O Yes

→ **If** Yes, **Heparin**[7235]**:** O No O Yes

→ **If** Yes, **Initial Administration**[7240]**:** O Pre-transseptal Puncture O Post-transseptal Puncture

→ **If** Yes, **Bivalirudin**[7245]**:** O No O Yes

→ **If** Yes, **Other**[7250]**:** O No O Yes

→ **If** Yes, **Anticoagulation Reversal**[7265]**:** (End of Procedure) O No O Yes

H. Intra or Post-Procedure Events (Complete for Each Lab Visit)

Intra or Post Procedure Events Occurred[9984]**:** O No O Yes → **If** Yes, specify the **Event(s), Event Date(s):**

Event[9985]	Event Occurred[9990]	Event Date(s)[9995]
Cardiovascular		
Cardiac Arrest	O No O Yes	mm / dd / yyyy
Myocardial Infarction	O No O Yes	mm / dd / yyyy
Air Embolism	O No O Yes	mm / dd / yyyy
Heart Failure	O No O Yes	mm / dd / yyyy
Heart Valve Damage	O No O Yes	mm / dd / yyyy
Left Atrial Thrombus	O No O Yes	mm / dd / yyyy
Pericardial Effusion (no intervention required)	O No O Yes	mm / dd / yyyy
Pericardial Effusion with tamponade (requiring percutaneous drainage)	O No O Yes	mm / dd / yyyy
Pericardial Effusion without tamponade (requiring percutaneous drainage)	O No O Yes	mm / dd / yyyy
Pericardial Effusion (requiring open cardiac surgery)	O No O Yes	mm / dd / yyyy
Pericarditis	O No O Yes	mm / dd / yyyy
Systemic		
Anaphylaxis	O No O Yes	mm / dd / yyyy
Arterial Thrombosis	O No O Yes	mm / dd / yyyy
Deep Vein Thrombosis	O No O Yes	mm / dd / yyyy
Systemic Thromboembolism (other than stroke) **(Complete Adjudication)**	O No O Yes	mm / dd / yyyy
Gastrointestinal/Genitourinary		
Esophageal Injury (resulting from TEE probe)	O No O Yes	mm / dd / yyyy
Hepatic Injury	O No O Yes	mm / dd / yyyy
New Requirement for Dialysis	O No O Yes	mm / dd / yyyy

H. Intra or Post-Procedure Events (Complete for Each Lab Visit)

Event[9985]	Event Occurred[9990]	Event Date(s)[9995]
Device		
Device Infection	O No O Yes	mm / dd / yyyy
Device Migration	O No O Yes	mm / dd / yyyy
Device Thrombus	O No O Yes	mm / dd / yyyy
Device Systemic Embolization (catheter retrieval)	O No O Yes	mm / dd / yyyy
Device Systemic Embolization (surgical retrieval)	O No O Yes	mm / dd / yyyy
Peripheral Vascular		
AV Fistula (no intervention required)	O No O Yes	mm / dd / yyyy
AV Fistula (requiring surgical repair)	O No O Yes	mm / dd / yyyy
Pseudoaneurysm (no intervention required)	O No O Yes	mm / dd / yyyy
Pseudoaneurysm (requiring endovascular repair)	O No O Yes	mm / dd / yyyy
Pseudoaneurysm (requiring surgical repair)	O No O Yes	mm / dd / yyyy
Pseudoaneurysm (requiring thrombin injection only)	O No O Yes	mm / dd / yyyy
Neurologic (Complete Adjudication)		
Hemorrhagic Stroke	O No O Yes	mm / dd / yyyy
Ischemic Stroke	O No O Yes	mm / dd / yyyy
Undetermined Stroke	O No O Yes	mm / dd / yyyy
TIA	O No O Yes	mm / dd / yyyy
Intracranial Hemorrhage (other than hemorrhagic stroke)	O No O Yes	mm / dd / yyyy
Bleeding (Complete Adjudication)		
Access Site Bleeding	O No O Yes	mm / dd / yyyy
Hematoma	O No O Yes	mm / dd / yyyy
Vascular Complications	O No O Yes	mm / dd / yyyy
GI Bleeding	O No O Yes	mm / dd / yyyy
Retroperitoneal Bleeding	O No O Yes	mm / dd / yyyy
Other Hemorrhage (non-intracranial)	O No O Yes	mm / dd / yyyy
Hemothorax (not requiring drainage)	O No O Yes	mm / dd / yyyy
Hemothorax (requiring drainage)	O No O Yes	mm / dd / yyyy
Pulmonary		
Pneumothorax (no intervention required)	O No O Yes	mm / dd / yyyy
Pneumothorax (requiring intervention)	O No O Yes	mm / dd / yyyy
Pleural Effusion	O No O Yes	mm / dd / yyyy
Pneumonia	O No O Yes	mm / dd / yyyy
Pulmonary Embolism	O No O Yes	mm / dd / yyyy
Respiratory Failure	O No O Yes	mm / dd / yyyy

I. Post Procedure Labs

Peak Creatinine[8500]**:** _____ mg/dL □ Not Drawn[8501] **Hemoglobin**[8505]**:** (Lowest) _____ g/dL □ Not Drawn[8506]

Creatinine[8510]**:** (at Discharge) _____ mg/dL □ Not Drawn[8511]

J. Discharge

Surgery[10000]**:** O No O Yes

Percutaneous Coronary Interventions (Other)[10001]**:** O No O Yes

Discharge Date[10100]**:** mm / dd / yyyy

Discharge Status[10105]**:** O Alive O Deceased

→ **If** Alive, **Discharge Location**[10110]**:**
O Home
O Extended care/TCU/rehab
O Other acute care hospital
O Skilled Nursing facility
O Other
O Left against medical advice (AMA)

→ **If** Alive, **Hospice Care**[10115]**:** O No O Yes

→ **If** Deceased, **Death During the Procedure**[10120]**:** O No O Yes

→ **If** Deceased, **Cause of Death**[10125]**:**
O Acute myocardial infarction
O Sudden cardiac death
O Heart failure
O Stroke
O Cardiovascular procedure
O Cardiovascular hemorrhage
O Other cardiovascular reason
O Pulmonary
O Renal
O Gastrointestinal
O Hepatobiliary
O Pancreatic
O Infection
O Inflammatory/Immunologic
O Hemorrhage
O Non-cardiovascular procedure or surgery
O Trauma
O Suicide
O Neurological
O Malignancy
O Other non-cardiovascular reason

Discharge Medications

Medications prescribed at discharge are not required for patients who expired, discharged to "Other acute care Hospital", "AMA", or are receiving Hospice Care.

Medication[10200]		Prescribed at Discharge[10205]			
		Yes	No - No Reason	No - Medical Reason	No - Pt. Reason
Antiplatelet	Aggrenox	O	O	O	O
	Aspirin (81 mg)	O	O	O	O
	Aspirin (325 mg)	O	O	O	O
	Durlaza	O	O	O	O
	Vorapaxar	O	O	O	O
P2Y12 Inhibitor	Clopidogrel	O	O	O	O
	Prasugrel	O	O	O	O
	Ticlopidine	O	O	O	O
	Ticagrelor	O	O	O	O
Anticoagulant	Warfarin	O	O	O	O
Non-vitamin K dependent oral anticoagulant	Apixaban	O	O	O	O
	Dabigatran	O	O	O	O
	Rivaroxaban	O	O	O	O
	Edoxaban	O	O	O	O
Bridging Therapy	Unfractionated Heparin	O	O	O	O
	Fondaparinux	O	O	O	O
	Low Molecular Wt Heparin	O	O	O	O
	Heparin Derivative	O	O	O	O

K. In-Hospital Adjudication (complete a separate adjudication for each adjudication event)

Last Name[2000]**:** **First Name**[2010]**:** **Patient ID**[2040]**:**

Procedure Start Date[7001]**:** **Other ID**[2045]**:** **Study Patient ID**[3030]**:**

Event[9985]**:** _____ **Event Date**[9995]**:** mm / dd / yyyy

Neurologic

Adjudication Status[12000]**:** O Alive O Deceased →**If** Deceased, **Date of Death**[12005]**:** mm / dd / yyyy

Symptom Onset Date[12010]**:** (approximate) mm / dd / yyyy

Neurologic Deficit with Rapid Onset[12015]**:** O No O Yes

→**If** Yes, **Clinical Presentation**[12020]**:** O Stroke-related O Non-Stroke-related

Diagnosis Confirmation by Neurology[12025]**:** O No O Yes

Brain Imaging Performed[12030]**:** O No O Yes

→**If** Yes, **Deficit Type**[12035]**:** O No deficit O Infarction O Hemorrhage O Both

→**If** Hemorrhage, **Type**[12040]**:** ☐ Intracerebral ☐ Subarachnoid ☐ Subdural

Subsequent IV rtPA Administered[12045]**:** O No O Yes

Subsequent Endovascular Therapeutic Intervention[12050]**:** O No O Yes

Symptoms Duration[12055]**:** O < 1 Hour O 1 – 24 Hours O > 24 Hours

Trauma[12060]**:** O No O Yes

Modified Rankin Scale (mRS)[12065]**:**
O 0: No symptoms at all
O 1: No significant disability despite symptoms
O 2: Slight disability
O 3: Moderate disability
O 4: Moderately severe disability
O 5: Severe disability
O 6: Death
☐ Not Administered[12066]

Procedure Related Neurologic Event[12070]**:** O Certain O Probable O Possible O Unlikely O Unclassifiable

Device Related Neurologic Event[12075]**:** O Certain O Probable O Possible O Unlikely O Unclassifiable

Bleeding

Adjudication Status[12080]**:** O Alive O Deceased →**If** Deceased, **Date of Death**[12085]**:** mm / dd / yyyy

Invasive Intervention Required[12090]**:** O No O Yes

RBC Transfusion[12095]**:** O No O Yes

→**If** Yes, **Number of RBC Units Transfused**[12100]**:** _____

→**If** Yes, **Hemoglobin Pre-Transfusion**[12105]**:** _____ g/dL

Diagnostic Imaging Performed [12110]**:** O No O Yes

End Organ Damage[12115]**:** O No O Yes

Major Surgery within Past 30 days[12120]**:** O No O Yes

Percutaneous Coronary Intervention within Past 30 days[12125]**:** O No O Yes

Procedure Related Bleeding Event[12130]**:** O Certain O Probable O Possible O Unlikely O Unclassifiable

Device Related Bleeding Event[12135]**:** O Certain O Probable O Possible O Unlikely O Unclassifiable

K. In-Hospital Adjudication (cont) (complete a separate adjudication for each adjudication event)

Systemic Thromboembolism

Adjudication Status[12150]**:** O Alive O Deceased →**If** Deceased, **Date of Death**[12155]**:** mm / dd / yyyy

→**If** Deceased, **Death Cause (End-Organ Hypoperfusion/ Systemic Thromboembolization/ Intervention)**[12160]**:** O No O Yes

Focal End-Organ Hypoperfusion Present[12165]**:** O No O Yes

Systemic Thromboembolization Imaging Evidence[12170]**:** O No O Yes

→**If** Yes, **Imaging Method**[12175]**:** □ Angiography □ CT scan □ MRI □ Ultrasound □ Other

Therapeutic Intervention Performed[12180]**:** O No O Yes

→**If** Yes, **Intervention Type**[12185]**:** □ Catheter □ Pharmacological □ Surgical □ Other

Medication[12140]		Current Medications at Time of Event[12145]	
		Yes	No
Antiplatelet	Aggrenox	O	O
	Aspirin (81 mg)	O	O
	Aspirin (325 mg)	O	O
	Durlaza	O	O
	Vorapaxar	O	O
P2Y12 Inhibitor	Clopidogrel	O	O
	Prasugrel	O	O
	Ticlopidine	O	O
	Ticagrelor	O	O
Anticoagulant	Warfarin	O	O
Non-vitamin K dependent oral anticoagulant	Apixaban	O	O
	Dabigatran	O	O
	Rivaroxaban	O	O
	Edoxaban	O	O
Bridging Therapy	Unfractionated Heparin	O	O
	Fondaparinux	O	O
	Low Molecular Wt Heparin	O	O
	Heparin Derivative	O	O

L. FOLLOW-UP

Follow-up should be performed at the following intervals post-procedure:
45 days (+/- 14 days), **6** months (+ 60 days/- 30 days), **1** year (+/- 60 days), **2** years (+/- 60 days)

Assessment Date[13000]: mm / dd / yyyy | **Follow-up Interval**[13001]: O 45 day O 6 month O 1 year O 2 year

Procedure Start Date/Time[7001/7002]: mm / dd / yyyy HH:MM

Method(s) to Determine Status: ☐ Office Visit[13005] ☐ Medical Records[13006] ☐ Letter from Medical Provider[13007] ☐ Phone Call[13008] ☐ Social Security Death Master File[13009] ☐ Hospitalized[13010] ☐ Other[13011]

Follow-up Status[13015]: O Alive O Deceased O Lost to Follow-up

→ **If** Deceased, **Date of Death**[13020]: mm / dd / yyyy

→ **If** Deceased, **Cause of Death**[13025]:

O Acute myocardial infarction	O Pulmonary	O Hemorrhage
O Sudden cardiac death	O Renal	O Non-cardiovascular procedure or surgery
O Heart failure	O Gastrointestinal	O Trauma
O Stroke	O Hepatobiliary	O Suicide
O Cardiovascular procedure	O Pancreatic	O Neurological
O Cardiovascular hemorrhage	O Infection	O Malignancy
O Other cardiovascular reason	O Inflammatory/Immunologic	O Other non-cardiovascular reason

DIAGNOSTIC STUDIES

LVEF Assessed[13030]: O No O Yes → **If** Yes, **LVEF**[13035]: _____ %

Transthoracic Echo (TTE) Performed[13040]: O No O Yes → **If** Yes, **Date of TTE**[13045]: mm / dd / yyyy

Transesophageal Echo Performed (TEE)[13050]: O No O Yes → **If** Yes, **Date of TEE**[13055]: mm / dd / yyyy

→ **If** Yes, **Atrial Thrombus Detected**[13060]: O No O Yes

Device Margin Residual Leak[13065]: _____ mm ☐ Not Assessed[13066]

PHYSICAL EXAM AND LABS

Creatinine[13070]: _____ mg/dL ☐ Not Drawn[13071] **Hemoglobin**[13075]: _____ g/dL ☐ Not Drawn[13076]

Modified Rankin Scale (mRS)[13080]:
O 0: No symptoms at all
O 1: No significant disability despite symptoms
O 2: Slight disability
O 3: Moderate disability
O 4: Moderately severe disability
O 5: Severe disability
O 6: Death
☐ Not Administered[13081]

BARTHEL INDEX EVALUATION[2]

Barthel Index Evaluation Performed[13085]: O No O Yes

→ **If** Yes,

Feeding[13086]:	O Unable	O Needs Help	O Independent	
Bathing[13087]:	O Dependent	O Independent		
Grooming[13088]:	O Needs Help	O Independent		
Dressing[13089]:	O Dependent	O Needs Help	O Independent	
Bowels[13090]:	O Incontinent	O Inconsistent	O Continent	
Bladder[13091]:	O Incontinent	O Inconsistent	O Continent	
Toilet Use[13092]:	O Dependent	O Needs Help	O Independent	
Transfers[13093]:	O Unable	O Major Assist Needed	O Minor Assist Needed	O Independent
Mobility[13094]:	O Immobile	O Wheelchair	O One Person Assist	O Independent
Stairs[13095]:	O Unable	O Needs Help	O Independent	

[2] MAHONEY FI, BARTHEL D. "FUNCTIONAL EVALUATION: THE BARTHEL INDEX." MARYLAND STATE MED JOURNAL 1965;14:56-61. USED WITH PERMISSION.

Follow-up Medications

Medication[13110]		Current Medications at Time of Follow-up[13115]			
		Yes	No - No Reason	No - Medical Reason	No - Pt. Reason
Antiplatelet	Aggrenox	O	O	O	O
	Aspirin (81 mg)	O	O	O	O
	Aspirin (325 mg)	O	O	O	O
	Durlaza	O	O	O	O
	Vorapaxar	O	O	O	O
P2Y12 Inhibitor	Clopidogrel	O	O	O	O
	Prasugrel	O	O	O	O
	Ticlopidine	O	O	O	O
	Ticagrelor	O	O	O	O
Anticoagulant	Warfarin	O	O	O	O
Non-vitamin K dependent oral anticoagulant	Apixaban	O	O	O	O
	Dabigatran	O	O	O	O
	Rivaroxaban	O	O	O	O
	Edoxaban	O	O	O	O
Bridging Therapy	Unfractionated Heparin	O	O	O	O
	Fondaparinux	O	O	O	O
	Low Molecular Wt Heparin	O	O	O	O
	Heparin Derivative	O	O	O	O

Follow-up Anticoagulation Therapy

Warfarin Discontinued[13120]**:** O No O Yes

→ **If** Yes, **Date**[13125]**:** mm / dd / yyyy

Warfarin Resumed[13130]**:** O No O Yes (Thrombotic Event) O Yes (Other)

→ **If** Yes, **Date**[13135]**:** mm / dd / yyyy

NOAC Discontinued[13140]**:** O No O Yes

→ **If** Yes, **Date**[13145]**:** mm / dd / yyyy

NOAC Resumed[13150]**:** O No O Yes (Thrombotic Event) O Yes (Other)

→ **If** Yes, **Date**[13155]**:** mm / dd / yyyy

Follow-up Events

Follow-up Events Occurred[13160]**:** O No O Yes → **If** Yes, specify the **Event(s), Event Date(s):**

Event[13165]	Event Occurred[13170]	Event Date(s)[13175]
Cardiovascular		
Myocardial Infarction	O No O Yes	mm / dd / yyyy
Endocarditis	O No O Yes	mm / dd / yyyy
Iatrogenic ASD (requiring intervention)	O No O Yes	mm / dd / yyyy
PCI	O No O Yes	mm / dd / yyyy
Pericardial Effusion (requiring drainage)	O No O Yes	mm / dd / yyyy
Pericarditis	O No O Yes	mm / dd / yyyy
Unplanned Cardiac Surgery	O No O Yes	mm / dd / yyyy
Unplanned Intervention	O No O Yes	mm / dd / yyyy
LAA Occlusion Reintervention	O No O Yes	mm / dd / yyyy
Systemic		
Systemic Thromboembolism (other than stroke) **(Complete Adjudication)**	O No O Yes	mm / dd / yyyy
New Requirement for Dialysis	O No O Yes	mm / dd / yyyy
Non-Device Related Readmission	O No O Yes	mm / dd / yyyy
Device		
Device Related Readmission	O No O Yes	mm / dd / yyyy
Device Fracture	O No O Yes	mm / dd / yyyy
Device Migration	O No O Yes	mm / dd / yyyy
Device Systemic Embolism	O No O Yes	mm / dd / yyyy
Device Thrombus	O No O Yes	mm / dd / yyyy
Neurologic (Complete Adjudication)		
Hemorrhagic Stroke	O No O Yes	mm / dd / yyyy
Ischemic Stroke	O No O Yes	mm / dd / yyyy
Undetermined Stroke	O No O Yes	mm / dd / yyyy
TIA	O No O Yes	mm / dd / yyyy
Intracranial Hemorrhage (other than hemorrhagic stroke)	O No O Yes	mm / dd / yyyy
Bleeding (Complete Adjudication)		
Access Site Bleeding	O No O Yes	mm / dd / yyyy
Hematoma	O No O Yes	mm / dd / yyyy
Vascular Complications	O No O Yes	mm / dd / yyyy
GI Bleeding	O No O Yes	mm / dd / yyyy
Retroperitoneal Bleeding	O No O Yes	mm / dd / yyyy
Other Hemorrhage (non-intracranial)	O No O Yes	mm / dd / yyyy

FOLLOW-UP ADJUDICATION (COMPLETE A SEPARATE ADJUDICATION FOR EACH ADJUDICATION EVENT)

Last Name[2000]**:** **First Name**[2010]**:** **Patient ID**[2040]**:**

Procedure Start Date[7001]**:** **Other ID**[2045]**:** **Study Patient ID**[3030]**:**

Follow-up Event[13165]**:** _____ **Follow-up Event Date**[13175]**:** mm / dd / yyyy

NEUROLOGIC

Follow-up Adjudication Status[13180]**:** O Alive O Deceased →**If** Deceased, **Date of Death**[13185]**:** mm / dd / yyyy

Date of Symptom Onset[13190]**:** (approximate) mm / dd / yyyy

Neurologic Deficit with Rapid Onset[13195]**:** O No O Yes

→**If** Yes, **Clinical Presentation**[13200]**:** O Stroke-related O Non-Stroke-related

Diagnosis Confirmation by Neurology[13205]**:** O No O Yes

Brain Imaging Performed[13210]**:** O No O Yes

→**If** Yes, **Deficit Type**[13215]**:** O No deficit O Infarction O Hemorrhage O Both

→**If** Hemorrhage, **Type**[13220]**:** ☐ Intracerebral ☐ Subarachnoid ☐ Subdural

Subsequent IV rtPA Administered[13225]**:** O No O Yes

Subsequent Endovascular Therapeutic Intervention[13230]**:** O No O Yes

Symptoms Duration[13235]**:** O < 1 Hour O 1 – 24 Hours O > 24 Hours

Trauma[13240]**:** O No O Yes

Modified Rankin Scale (mRS)[13245]**:**
O 0: No symptoms at all
O 1: No significant disability despite symptoms
O 2: Slight disability
O 3: Moderate disability
O 4: Moderately severe disability
O 5: Severe disability
O 6: Death
☐ Not Administered[13246]

Procedure Related Neurologic Event[13250]**:** O Certain O Probable O Possible O Unlikely O Unclassifiable

Device Related Neurologic Event[13255]**:** O Certain O Probable O Possible O Unlikely O Unclassifiable

BLEEDING

Follow-up Adjudication Status[13260]**:** O Alive O Deceased →**If** Deceased, **Date of Death**[13265]**:** mm / dd / yyyy

Invasive Intervention Required[13270]**:** O No O Yes

RBC Transfusion[13275]**:** O No O Yes

→**If** Yes, **Number of RBC Units Transfused**[13280]**:** _____

→**If** Yes, **Hemoglobin Pre-Transfusion**[13285]**:** _____ g/dL

Diagnostic Imaging Performed [13290]**:** O No O Yes

End Organ Damage[13295]**:** O No O Yes

Bleeding Event Readmission[13300]**:** O No O Yes

Major Surgery within Past 30 days[13305]**:** O No O Yes

Percutaneous Coronary Intervention within Past 30 days[13310]**:** O No O Yes

Procedure Related Bleeding Event[13315]**:** O Certain O Probable O Possible O Unlikely O Unclassifiable

Device Related Bleeding Event[13320]**:** O Certain O Probable O Possible O Unlikely O Unclassifiable

FOLLOW-UP ADJUDICATION (CONT) (COMPLETE A SEPARATE ADJUDICATION FOR EACH ADJUDICATION EVENT)

SYSTEMIC THROMBOEMBOLISM

Follow-up Adjudication Status[13335]**:** O Alive O Deceased →**If** Deceased, **Date of Death**[13340]**:** mm / dd / yyyy

→**If** Deceased, **Death Cause (End-Organ Hypoperfusion/ Systemic Thromboembolization/ Intervention)**[13345]**:** O No O Yes

Focal End-Organ Hypoperfusion Present[13350]**:** O No O Yes

Systemic Thromboembolization Imaging Evidence[13355]**:** O No O Yes

→**If** Yes, **Imaging Method**[13360]**:** □ Angiography □ CT scan □ MRI □ Ultrasound □ Other

Therapeutic Intervention Performed[13365]**:** O No O Yes

→**If** Yes, **Intervention Type**[13370]**:** □ Catheter □ Pharmacological □ Surgical □ Other

MEDICATION[13325]		CURRENT MEDICATIONS AT TIME OF EVENT[13330]	
		YES	NO
ANTIPLATELET	Aggrenox	O	O
	Aspirin (81 mg)	O	O
	Aspirin (325 mg)	O	O
	Durlaza	O	O
	Vorapaxar	O	O
P2Y12 INHIBITOR	Clopidogrel	O	O
	Prasugrel	O	O
	Ticlopidine	O	O
	Ticagrelor	O	O
ANTICOAGULANT	Warfarin	O	O
NON-VITAMIN K DEPENDENT ORAL ANTICOAGULANT	Apixaban	O	O
	Dabigatran	O	O
	Rivaroxaban	O	O
	Edoxaban	O	O
BRIDGING THERAPY	Unfractionated Heparin	O	O
	Fondaparinux	O	O
	Low Molecular Wt Heparin	O	O
	Heparin Derivative	O	O