NCDR® Data Collection Form v1.2 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]: | **MBI**[12846]:

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			
CHA_2DS_2-VASc Stroke[4030]:	O No	O Yes			
CHA_2DS_2-VASc TIA[4035]:	O No	O Yes			

→ **If** Yes, **Vascular Disease Type**[4050]: (Select all that apply)
☐ Prior MI ☐ PAD ☐ Known Aortic Plaque
☐ CAD* ☐ PCI* ☐ CABG* ☐ Carotid Disease*
**This selection is not part of the original validated vascular disease criterion for the CHA2DS2-VASc score.*

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]: ☐ Not Administered[6086]

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

F. Pre-Procedure Medications

Medication[6985]		Pre-Proc Medication Administered[6990]			
		Past	Current	Held	Never
Antiplatelet	Aspirin (81-100 mg)	O	O	O	O
	Aspirin (101-324 mg)	O	O	O	O
	Aspirin 325 mg	O	O	O	O
	Aspirin/Dipyridamole	O	O	O	O
	Vorapaxar	O	O	O	O
P2Y12 Inhibitor	Cangrelor	O	O	O	O
	Clopidogrel	O	O	O	O
	Prasugrel	O	O	O	O
	Ticlopidine	O	O	O	O
	Ticagrelor	O	O	O	O
	Other P2Y12 Inhibitor	O	O	O	O
Anticoagulant	Warfarin	O	O	O	O
Direct 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 Moderate Sedation/Analgesia (Conscious Sedation) O Deep Sedation/Analgesia 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
□ Transcatheter device retrieval
□ Surgical device retrieval
□ Unanticipated patient condition
□ Appendage too large (for device implant)
□ Decompensation in patient condition
□ Device release criteria not met
□ Device associated thrombus developed during procedure
□ Patient/Family choice
□ Appendage too small (for device implant)
□ Device related
□ Epicardial access issue

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

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
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
DEVICE		
Device Explant	O No O Yes	mm / dd / yyyy
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

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

Event[9985]	Event Occurred[9990]	Event Date(s)[9995]
Peripheral Vascular*		
When selecting Peripheral Vascular events requiring endovascular, surgical, or thrombin injection interventions, also code **Vascular Complications (as the events meet the definition) and complete the Bleeding Adjudication fields.*		
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
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
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. POST PROCEDURE MEDICATION STRATEGIES (INTENDED AT THE TIME OF IMPLANT)

Some medications and/or strategy options listed below are not in accordance with the device's directions for use. Please consult the device's label for further information.

Medication[8515]	Planned Strategy[8520]
Aspirin (81-100 mg)	O None O Implant until LAA seal O Implant until 6 months post-implant O Implant and continue indefinitely O Initiate at LAA seal and continue indefinitely
Aspirin (101-324 mg)	O None O Implant until LAA seal O Implant until 6 months post-implant O Implant and continue indefinitely O Initiate at LAA seal and continue indefinitely
Aspirin 325 mg	O None O Implant and continue indefinitely O Initiate at LAA seal and continue indefinitely O Implant and discontinue at any undetermined point in time O Initiate after 6 months and continue indefinitely
P2Y12	O None O Initiate at LAA seal and stop 6 months post-implant O Implant and stop at <= 3 months O Implant and stop at > 3 months or <= 6 months O Implant and continue at > 6 months
DOAC	O None O Implant until LAA seal O Implant and continue indefinitely O Implant and discontinue at < 45 days
Warfarin	O None O Implant until LAA seal O Implant and discontinue at < 45 days

→ **If** any Strategy, **Reason**[8525]**:** (Select all that apply)

□ FDA label dosing regimen
□ Continue pre-implant regimen
□ Hemorrhagic complication
□ Non-hemorrhagic complication
□ Known drug resistance
□ Drug intolerance
□ Cost
□ Patient preference

K. 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]				→ IF YES, DOSE[10207]		
		YES	NO – NO REASON	NO – MEDICAL REASON	NO – PT. REASON	81-100 MG	101-324 MG	325 MG
ANTIPLATELET	Aspirin	O	O	O	O	O	O	O
	Aspirin/Dipyridamole	O	O	O	O			
	Vorapaxar	O	O	O	O			
P2Y12 INHIBITOR	Cangrelor	O	O	O	O			
	Clopidogrel	O	O	O	O			
	Prasugrel	O	O	O	O			
	Ticlopidine	O	O	O	O			
	Ticagrelor	O	O	O	O			
	Other P2Y12 Inhibitor	O	O	O	O			
ANTICOAGULANT	Warfarin	O	O	O	O			
DIRECT 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			

L. 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]: (Lowest) _____ 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

L. 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	Aspirin (81-100 mg)	O	O
	Aspirin (101-324 mg)	O	O
	Aspirin 325 mg	O	O
	Aspirin/Dipyridamole	O	O
	Vorapaxar	O	O
P2Y12 Inhibitor	Cangrelor	O	O
	Clopidogrel	O	O
	Prasugrel	O	O
	Ticlopidine	O	O
	Ticagrelor	O	O
	Other P2Y12 Inhibitor	O	O
Anticoagulant	Warfarin	O	O
Direct 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

M. 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

Cardiac CT Performed[13056]: O No O Yes → **If** Yes, **Date of Cardiac CT**[13057]: mm / dd / yyyy

Cardiac MRI Performed[13058]: O No O Yes → **If** Yes, **Date of Cardiac MRI**[13059]: mm / dd / yyyy

→ **If** Yes (TEE) **OR** Yes (Cardiac CT) **OR** Yes (Cardiac MRI), **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]: (Lowest) _____ 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]

L. FOLLOW-UP

PHYSICAL EXAM AND LABS

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]				→ IF YES, DOSE[13117]		
		YES	NO – NO REASON	NO – MEDICAL REASON	NO – PT. REASON	81-100 MG	101-324 MG	325 MG
ANTIPLATELET	Aspirin	O	O	O	O	O	O	O
	Aspirin/Dipyridamole	O	O	O	O			
	Vorapaxar	O	O	O	O			
P2Y12 INHIBITOR	Cangrelor	O	O	O	O			
	Clopidogrel	O	O	O	O			
	Prasugrel	O	O	O	O			
	Ticlopidine	O	O	O	O			
	Ticagrelor	O	O	O	O			
	Other P2Y12 Inhibitor	O	O	O	O			
ANTICOAGULANT	Warfarin	O	O	O	O			
DIRECT 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 (DOAC) Discontinued[13140]: O No O Yes

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

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

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

Aspirin Discontinued[13375]: O No O Yes

→ **If** Yes, **Date**[13380]: mm / dd / yyyy

Aspirin Resumed[13385]: O No O Yes (Thrombotic Event) O Yes (Other)

→ **If** Yes, **Date**[13390]: mm / dd / yyyy

P2Y12 Discontinued[13400]: O No O Yes

→ **If** Yes, **Date**[13405]: mm / dd / yyyy

P2Y12 Resumed[13410]: O No O Yes (Thrombotic Event) O Yes (Other)

→ **If** Yes, **Date**[13415]: 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
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 Explant	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

FOLLOW-UP EVENTS (CONT.)

Event[13165]	Event Occurred[13170]	Event Date(s)[13175]
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
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
PERIPHERAL VASCULAR*		
When selecting Peripheral Vascular events requiring endovascular, surgical, or thrombin injection interventions, also code **Vascular Complications (as the events meet the definition) and complete the Bleeding Adjudication fields.*		
AV Fistula (requiring surgical repair)	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

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]: (Lowest) _____ 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	Aspirin (81-100 mg)	O	O
	Aspirin (101-324 mg)	O	O
	Aspirin 325 mg	O	O
	Aspirin/Dipyridamole	O	O
	Vorapaxar	O	O
P2Y12 INHIBITOR	Cangrelor	O	O
	Clopidogrel	O	O
	Prasugrel	O	O
	Ticlopidine	O	O
	Ticagrelor	O	O
	Other P2Y12 Inhibitor	O	O
ANTICOAGULANT	Warfarin	O	O
DIRECT 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