Mitral Leaflet Clip **Data Collection Form v2.1**

STS/ACC TVT Registry™

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	**Hispanic or Latino Ethnicity**[2076]: O No O Yes

Race: (check all that apply)
□ White[2070] □ Black/African American[2071] □ Asian[2072]
□ American Indian/Alaskan Native[2073] □ Native Hawaiian/Pacific Islander[2074]

Arrival Date/Time[3000,3001]: mm / dd / yyyy HH:MM

Residence[3003]: O Home w/no health-aid O Home w/health-aid O Long-term care O Other O Not Documented

Insurance Payors: (check all that apply)
□ Private Health Insurance[3005] □ Medicare[3006] □ Medicaid[3007] □ Military Health Care[3008]
□ State-Specific Plan (non-Medicaid)[3009] □ Indian Health Service[3010] □ Non-US Insurance[3011] □ None[3012]

HIC[3015]: **Research Study**[3030]: O No O Yes **If** Yes, **Study Patient ID**[3032]:

Infective Endocarditis[4000]: O No O Yes	**Prior Non Aortic Valve Procedure**[4095]: O No O Yes
If Yes, **Infective Endocarditis Type**[4005]: O Treated O Active	**If** Yes, **Most Recent MV Procedure Date**[4097]: mm / dd / yyyy **If** Yes, **MV Repair – Surgical**[4110]: O No O Yes
Heart Failure Hospitalization w/in Past Year[4006]: O No O Yes O Not Documented	**If** Yes, **Mitral Annuloplasty Ring–Surgical**[4111]: O No O Yes – partial O Yes – circumferential O Not Documented
Permanent Pacemaker[4010]: O No O Yes	
If Yes, **CRT**[4013]: O No O Yes	**If** Yes**, MV Transcatheter Intervention**[4112]: O No O Yes
Previous ICD[4015]: O No O Yes	**If** Yes, **Mitral Transcather Type**[4113]: O Leaflet clip O Direct annuloplasty intervention O Coronary sinus based intervention O Valve-in-native Valve O Valve-in-Valve O Other
If Yes, **CRT–D**[4016]: O No O Yes	
Prior PCI[4020]: O No O Yes	
Prior CABG[4030]: O No O Yes	
# Previous Cardiac Surgeries[4055]: O 0 O 1 O 2 O 3 O >=4	
Prior Aortic Valve Procedure[4060]: O No O Yes	**If** Yes, **Prior Tricuspid Valve Repair/Replacement**[4118]: O No O Yes
If Yes, **AV Replacement – Surgical**[4070]: O No O Yes	
If Yes, **AV Repair – Surgical**[4080]: O No O Yes	**If** Yes, **Prior Pulmonic Valve Repair/Replacement**[4119]: O No O Yes
If Yes, **AV Transcatheter Valve Replacement**[4090]: O No O Yes	

Prior Stroke[4120]: O No O Yes	**Diabetes Mellitus**[4165]: O No O Yes
If Yes, **Most Recent Stroke Date**[4125]: mm / dd / yyyy	**If** Yes, **Diabetes Therapy**[4170]: O None O Diet O Oral O Insulin O Other
Transient Ischemic Attack[4130]: O No O Yes	
Carotid Stenosis[4135]: O None O Right O Left O Both O NA	**Currently on Dialysis**[4175]: O No O Yes
If Yes, **Prior CEA/CAS**[4140]: O No O Yes	**Chronic Lung Disease**[4180]: O None O Mild O Moderate O Severe
Peripheral Arterial Disease[4145]: O No O Yes	**Home Oxygen**[4181]: O No O Yes
Current Smoker[4150] (w/in 1 year): O No O Yes	**Hostile Chest**[4182]: O No O Yes
Hypertension[4155]: O No O Yes	**Immunocompromise Present**[4185]: O No O Yes

HOME MEDICATIONS

ACE or ARB (any)[4200,4205] :	O No	O Yes	**Diuretics – Aldosterone Antagonists**[4200,4205] :	O No	O Yes
Anticoagulants (any)[4200,4205]:	O No	O Yes	**Diuretics – Loop diuretic**[4200,4205] :	O No	O Yes
Aspirin (alone)[4200,4205]:	O No	O Yes	**If** Loop Diuretic, **Dose**[4210]:_ mg		
Aspirin (dual antiplatelet therapy)[4200,4205]:	O No	O Yes	**Diuretics – Thiazides**[4200,4205]:	O No	O Yes
Beta Blockers (any)[4200,4205]:	O No	O Yes	**Diuretics** (not otherwise specified)[4200,4205]:	O No	O Yes

D. PRE-PROCEDURE STATUS (COMPLETE FOR THE PROCEDURE)

CAD Presentation[5000]: O No Sxs, no angina *(14 days)* O Sx unlikely to be ischemic *(14 days)* O Stable angina *(42 days)*

O Unstable angina *(60 days)* O Non-STEMI *(7 days)* O STEMI *(7 days)*

Prior MI[5005]: O No O Yes à**If** Yes, **Prior MI Timeframe**[5010]: O < 30 Days O >= 30 days

Cardiomyopathy[5012]: O No O Yes – Ischemic O Yes – Non-ischemic

Heart Failure w/in 2 Weeks[5020]:	O No	O Yes	**STS Risk Score** (MV replace)[5106]:____ %		
NYHA Class w/in 2 Weeks[5025]:	O I O II	O III O IV	**STS Risk Score** (MV repair)[5107]: ___ %		
Cardiogenic Shock w/in 24 Hours[5030]:	O No	O Yes	**Six Minute Walk Test**[5115]:		
Cardiac Arrest w/in 24 Hours[5035]:	O No	O Yes	O Performed O Not performed – non-cardiac reason O Not performed – cardiac reason O Not performed – patient not willing to walk O Not performed by site		
Porcelain Aorta[5045]:	O No	O Yes			
Atrial Fibrillation/Flutter[5050]:	O No	O Yes	**Test Date**[5116]: mm / dd / yyyy		
If Yes, **AF Class w/in past 30 days**[5052]: O None O Persistent O Paroxysmal			**Total Distance**[5117]:_____ ft		

KCCQ-12 Performed[5169]: O No O Yes

If Yes**, KCCQ-12**[5170-5181]: **Q1a:**____ **Q1b:**____ **Q1c:**____ **Q2:** ___ **Q3:** ___ **Q4:** ___

(See separate questionnaire)

Q5: ___ **Q6:** ___ **Q7:** ___ **Q8a:**____ **Q8b:**____ **Q8c:** ___

CLINICAL DATA (CLOSEST TO THE PROCEDURE)

Height[5200]:_____ cm	**Weight**[5205]:_____ kg		**Hemoglobin**[5250]:___ g/dL	□ Not Drawn[5251]	
Creatinine[5255]:___ mg/dL	□ Not Drawn[5256]		**BNP**[5277]:_ pg/mL (OR)	**NT proBNP**[5278]:_ pg/mL	
FEV1 Predicted[5280]:___ %	□ Not Performed[5281]			□ Not Drawn[5279]	
DLCO (Adjusted)[5285]:___ %	□ Not Performed[5286]		**QRS Duration**[5290]:____ msec	□ Ventricular Paced[5291]	

MEDICATIONS (ADMINISTERED WITHIN 24 HOURS PRIOR TO THE PROCEDURE)

Inotropes[5400,5405](positive): O No O Yes O Contraindicated O Blinded

DIAGNOSTIC CATH FINDINGS

Number of Diseased Vessels[5506]: O None O 1 O 2 O 3

Left Main Stenosis >=50%[5507]: O No O Yes

LVEF[5565]: ____ % □ LVEF Not Assessed[5566]

Cardiac Output[5567]:_____ L/min □ Not Performed[5569]

Pulmonary Capillary Wedge Pressure[5590]: ____ mmHg □ Not Measured[5591]

Pulmonary Artery Pressure (mean)[5593]: ____ mmHg □ Not Measured[5594]

Pulmonary Artery Pressure (systolic)[5596]: ____ mmHg □ Not Measured[5597]

Right Atrial Pressure/CVP (mean)[5598]: ____ mmHg □ Not Measured[5599]

ECHOCARDIOGRAM FINDINGS

Left Ventricular Internal Systolic Dimension[5595]: _ cm □ Not Measured[5608]

Left Ventricular Internal Diastolic Dimension[5600]: _ cm □ Not Measured[5609]

Left Ventricular End Systolic Volume[5601]: _ ml □ Not Measured[5602]

Left Ventricular End Diastolic Volume[5603]: _ ml □ Not Measured[5604]

Left Atrial Volume[5606]:_ mL (OR) **LA Volume Index**[5607]:_ mL/m^2

Aortic Regurgitation[5630] (highest): O None O Trace/Trivial O 1+ (mild) O 2+ (moderate) O 3-4+ (severe)

Aortic Stenosis[5665]: O No O Yes

Mitral Valve Disease[5685]: O No O Yes **If** Yes, complete the following:

Mitral Regurgitation[5695] (highest): O None O Trace/Trivial O 1+ (mild) O 2+ (moderate) O 3+ (moderate – severe) O 4+ (severe)

Note: According to American Society of Echocardiography Guidelines

Effective Orifice Area (EOA) or **EROA** [5698]: ____ cm^2 **Method of Assessment**[5699]: O 3D Planimetry O PISA O Quantitative Doppler O Other

Mitral Valve Stenosis[5705]: O No O Yes

MV Area[5710]: ____ cm^2 **MV Mean Gradient**[5715] (highest):_____ mmHg

Tricuspid Regurgitation[5735]: O None O Trace/Trivial O Mild O Moderate O Severe

Mitral Valve Disease Etiology (check all that apply):

□ **Functional Mitral Regurgitation (FMR)**[5745] □ **Degenerative Mitral Regurgitation (DMR)**[5746] □ **Post – Inflammatory**[5747]

□ **Endocarditis**[5748] □ **Other/Indeterminate**[5749]

If FMR is Yes, **Functional Type**[5755]: O Ischemic-acute, post infarction O Ischemic-chronic O Non-ischemic dilated cardiomyopathy O Restrictive cardiomyopathy O Hypertrophic cardiomyopathy O Pure annular dilation (w/normal LV systolic fx) O Not Documented

If DMR is Yes, **Leaflet Prolapse**[5760]: O None O Anterior O Posterior O Bi-leaflet O Not Documented

If DMR is Yes, **Leaflet Flail**[5765]: O None O Anterior O Posterior O Bi-leaflet O Not Documented

If Inflammatory is Yes, **Type**[5770]: O Idiopathic O Prior radiation Rx O Collagen vascular disease O Drug induced O Rheumatic fever history O Not Documented

ECHOCARDIOGRAM FINDINGS

Mitral Leaflet Calcification[5810]**:** O Yes O No O Not Documented

Leaflet Tethering[5775]**:** O None O Anterior O Posterior O Bi-leaflet O Not Documented

Mitral Annular Calcification[5800]**:** O Yes O No O Not Documented

Carpentier's Functional Class of Mitral Regurgitation[5820]**:** O Type I O Type II O Type IIIa O Type IIIb O Not Documented

LEAFLET CLIP PROCEDURE REASONS/INDICATIONS (CHECK ALL THAT APPLY – AT LEAST ONE INDICATION SHOULD BE SELECTED)

□ **Frailty**[5900] *(assessed by in-person cardiac surgeon consultation)* □ **Hostile Chest**[5901]

□ **Severe Liver Disease (Cirrhosis or MELD score >12)**[5902] □ **Porcelain Aorta**[5903] *(or extensively calcified ascending aorta)*

□ **Predicted STS MV Repair Operative Mortality Risk of >=6%** *(for patients deemed likely to undergo MV repair)*[5905]

□ **Predicted STS MV Replacement Operative Mort Risk >=8%** *(for patients deemed likely to undergo MV replacement)*[5904]

□ **Unusual Extenuating Circumstance**[5906] **If** Unusual Extenuating Circumstance, check all that apply:

□ **Right Ventricular Dysfunction w/Severe Tricuspid Regurg**[5907] □ **Chemotherapy for Malignancy**[5908] □ **Major Bleeding Diathesis**[5909]

□ **Immobility**[5910] □ **AIDS**[5911] □ **Severe Dementia**[5912] □ **High Risk of Aspiration**[5913] □ **IMA at High Risk of Injury**[5914]

□ **Other**[5915] **If** Other , **Specify** [5916] (provide reason why patient is prohibitive risk): _____

E. PROCEDURE INFORMATION (COMPLETE FOR EACH LEAFLET CLIP PROCEDURE)

Procedures

□ **Transcatheter Aortic Valve Replacement**[6600] □ **Transcatheter Mitral Valve Replacement**[6601] □ **Mitral Leaflet Clip Procedure**[6602]

Other Procedure Performed Concurrently[6620]**:** O No O Yes – PCI O Yes – Other

Operator A Name[6000,6005,6010]**:** **Operator A NPI**[6015]**:**

Operator B Name[6020,6025,6030]**:** **Operator B NPI**[6035]**:**

Procedure Start Date[6040,6041]**:** mm / dd / yyyy HH:MM **Procedure Stop Date**[6045,6046]**:** mm / dd / yyyy HH:MM

Procedure Status[6055]**:** O Elective O Urgent O Emergency O Salvage

Type of Anesthesia[6110]**:** O General anesthesia O Moderate sedation O Epidural O Combination

Guiding Cath Access Site[6212]**:** O Right femoral vein O Left femoral vein O Jugular vein O Other vein

Steerable Guide Model ID[26180]**:**_____ **Steerable Guide Cath Serial Number**[26182]**:** _____

Leaflet Clip Counter[26240]**:**	**Leaflet Clip #1**	**Leaflet Clip #2**	**Leaflet Clip #3**
Leaflet Clip Model ID [26245]**:**	Refer to Device List	Refer to Device List	Refer to Device List
Leaflet Clip Serial #[26250]**:**			
UDI [26255, 26260, 26265]	(future)	(future)	(future)
Location[26270]**:**	O A1P1 O A2P2 O A3P3	O A1P1 O A2P2 O A3P3	O A1P1 O A2P2 O A3P3
Clip Deployed[26275]**:**	O No O Yes	O No O Yes	O No O Yes
If No, **Reason**[26280]**:**	O Inability to grasp leaflets O Inability to reduce MR O Mitral stenosis O MV injury O Device malfunction O Adverse event O Other	O Inability to grasp leaflets O Inability to reduce MR O Mitral stenosis O MV injury O Device malfunction O Adverse event O Other	O Inability to grasp leaflets O Inability to reduce MR O Mitral stenosis O MV injury O Device malfunction O Adverse event O Other

POST IMPLANT

Mitral Regurgitation[26285]**:** O None O Trace/Trivial O 1+ (mild) O 2+ (moderate) O 3+ (moderate – severe) O 4+ (severe)

Note: According to American Society of Echocardiography Guidelines

MV Mean Gradient[26290]**:**_____ mmHg

Conversion to Open Heart Surgery[26105]**:** O No O Yes

Mechanical Assist Device[26140]**:** O No O Yes

If Yes, **Timing**[26141]**:** O Pre-procedure O Intra-procedure O Post-procedure

If Yes, **Type**[26142]**:** O IABP O Catheter-based assist device

Cardiopulmonary Bypass Used[6100]**:** O No O Yes

If Yes, **Status**[6101]**:** O Elective O Emergent **If** Yes, **CPB Time** [6105]**:**____ mins

Radiation Dose Measurement Method[6455]**:** O Single Plane O Biplane

Fluoroscopy Time[6460]**:**_____ mins **Cumulative Air Kerma**[6465]**:**_ mGy

Dose Area Product[6470]**:**____ **DAP Units**[6475]**:** O Gy-cm^2 O cGy-cm^2 O mGy-cm^2 O µGy-M^2

Procedure Duration	Start Time	Stop Time
Procedure Room	Arrival Date/Time[26060,26061] mm / dd / yyyy HH:MM	
Anesthesia	Induction[26070] HH:MM	Discontinuation[26071] HH:MM
Procedure Access	Vascular or TEE Access[26075] HH:MM	Last Cath/TEE Removed[26076] HH:MM
Transseptal Access	Transseptal Access[26080] HH:MM	Septum Crossed[26081] HH:MM
Device	SCG in Intra-atrial Septum[26086] HH:MM	Delivery System Retracted[26091] HH:MM
		SCG Device Removal (from fem vein)[26096] HH:MM

F. ADVERSE EVENTS, INTERVENTIONS AND SURGERIES (COMPLETE FOR EACH PROCEDURE. SPECIFY EVENT DATE FOR EACH EVENT OCCURRENCE.)

Intra or Post Procedure Events Occurred[7300]**:** O No O Yes **If** Yes, specify the **Event**[7301] **and Event Date(s)**[7302]**:**

Cardiac	**Atrial Fibrillation** (new onset)[E006]**:** mm / dd / yyyy	**Neuro**	**Transient Ischemic Attack**[E010] (complete Adjudication)**:** mm / dd / yyyy
	Cardiac Arrest[E005]**:** mm / dd / yyyy		**Ischemic Stroke**[E011] (complete Adjudication)**:** mm / dd / yyyy
	Endocarditis[E003]**:** mm / dd / yyyy		**Hemorrhagic Stroke**[E012] (complete Adjudication)**:** mm / dd / yyyy
	Myocardial Infarction[E059]**:** mm / dd / yyyy		**Stroke (Undetermined Type)**[E013] (complete Adjudication)**:** mm / dd / yyyy
	Perforation (w/ or w/o Tamponade)[E009]**:** mm / dd / yyyy	**Device/Delivery System**	**Single Leaflet Device Attachment** [E049]**:** mm / dd / yyyy
Valve	**Mitral Leaflet Injury** (detected during surgery)[E045]**:** mm / dd / yyyy		**Complete Detachment of Leaflet Clip** (from valve leaflets)[E051]**:** mm / dd / yyyy
	Mitral Leaflet Injury (ascertained by echo)[E046]**:** mm / dd / yyyy		**Device Embolization** [E050]**:** mm / dd / yyyy
	Mitral Subvalvular Injury (detected during surgery)[E047]**:** mm / dd / yyyy		**Delivery system component embolization**[E058]**:** mm / dd / yyyy
	Mitral Subvalvular Injury (ascertained by echo)[E048]: mm / dd / yyyy		**Device Thrombosis**[E027]**:** mm / dd / yyyy
Renal	**New Requirement for Dialysis**[E029]**:** mm / dd / yyyy		**Other Device/Delivery System Related Event**[E028]**:** mm / dd / yyyy

F. Adverse Events, Interventions and Surgeries (Complete for Each Procedure. Specify event date for each event occurrence.)

Intra or Post Procedure Events Occurred[7300]: O No O Yes **If** Yes, specify the **Event**[7301] **and Event Date(s)**[7302]:

Bleed/Vascular

- **Bleeding at Access Site**[E017]: mm / dd / yyyy
- **Hematoma at Access Site**[E018]: mm / dd / yyyy
- **Retroperitoneal Bleeding**[E019]: mm / dd / yyyy
- **GI Bleed**[E020]: mm / dd / yyyy
- **GU Bleed**[E021]: mm / dd / yyyy
- **Other Bleed**[E022]: mm / dd / yyyy
- **Transseptal Complication**[E052]: mm / dd / yyyy

Vascular

- **Major Vascular Complication**[E041]: mm / dd / yyyy
- **Minor Vascular Complication**[E042]: mm / dd / yyyy

Additional Procedures

- **Mitral Valve Re-intervention**[E053] (complete Adjudication): mm / dd / yyyy
- **Unplanned Other Cardiac Surgery or Intervention**[E031] (not MVR): mm / dd / yyyy
- **Unplanned Vascular Surgery or Intervention**[E032] (for Bleeding or Access Site Complication): mm / dd / yyyy
- **ASD Closure Due To Transseptal Catheterization**[E054]: mm / dd / yyyy

G. Post-Procedure Labs and Tests

Lowest Hemoglobin[8040]:____ g/dL □ Not Drawn[8041] **Highest Creatinine**[8050]:_ mg/dL □ Not Drawn[8051]

Echocardiogram[8065]: O Not Performed O Yes - TTE O Yes - TEE **If** Yes, complete the following:

Date[8070]: mm / dd / yyyy

Mitral Regurgitation[8075]: O None O Trace/Trivial O 1+ (mild) O 2+ (moderate) O 3+ (moderate – severe) O 4+ (severe)

Note: According to American Society of Echocardiography Guidelines

Effective Orifice Area (EOA) or EROA [8122]:____ cm^2 **Method of Assessment**[8125]: O 3D Planimetry O PISA O Quantitative Doppler O Other

Mean Mitral Gradient[8130]:____ mmHg

H. Discharge (Complete for each episode of care)

RBC/Whole Blood Transfusion[9011]: O No O Yes **If** Yes, # **Units Transfused**[9012]:_____ *Note: Code the total # of units between start of the procedure and discharge*

Number of Hours in ICU[9040]: ____

Discharge Date[9045]: mm / dd / yyyy **Discharge Status**[9050]: O Alive O Deceased

If Alive, **Discharge Location**[9055]: O Home O Extended care/TCU/rehab O Other acute care hospital O Nursing home O Hospice O Other O Left against medical advice (AMA)

If Deceased, **Death in Lab/OR**[9060]: O No O Yes

If Deceased, **Primary Cause of Death**[9065]: O Cardiac O Neurologic O Renal O Vascular O Infection O Valvular O Pulmonary O Unknown O Other

Discharge Medications (not required for pts who expired or were discharged to 'Other acute care Hospital', 'Hospice', or 'AMA')

ACE/ARB[9100,9105] (any):	O No	O Yes	O Contraindicated	O Blinded
Anticoagulants (any)[9100,9105]	O No	O Yes	O Contraindicated	O Blinded
Aspirin (alone)[9100,9105]:	O No	O Yes	O Contraindicated	O Blinded
Aspirin (dual antiplatelet therapy) [9100,9105]:	O No	O Yes	O Contraindicated	O Blinded
Beta Blockers (any)[9100,9105]:	O No	O Yes	O Contraindicated	O Blinded
Diuretics – Aldosterone Antagonists[9100,9105]:	O No	O Yes	O Contraindicated	O Blinded
Diuretics – Loop[9100,9105]:	O No	O Yes	O Contraindicated	O Blinded
If Loop Diuretic, **Dose**[9110]:_ mg				
Diuretics (not otherwise specified)[9100,9105]:	O No	O Yes	O Contraindicated	O Blinded
Diuretics – Thiazides[9100,9105]:	O No	O Yes	O Contraindicated	O Blinded

I. FOLLOW-UP (30 DAYS, 1 YEAR FROM DATE OF PROCEDURE)

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

Reference Procedure Start Date[6040]**:** mm / dd / yyyy **Other ID**[2045]**:** **Study Patient ID**[3032]**:** (optional)

Assessment Date[10000]**:** mm / dd / yyyy (If the patient has not been discharged at 30 days, capture the 30 day F/U while still in the facility.)

Primary Method to Determine Status[10005]**:** O Clinic O Medical record O Letter from medical provider O Phone call to patient/family O Social Security death master file O Other

Residence[10008]**:** O Home w/no health-aid O Home w/health-aid O Long-term care O Other O Not documented

Status[10010]**:** O Alive O Deceased O Lost to follow-up O Withdrawn

If Deceased, **Primary Cause of Death**[10015]**:** O Cardiac O Neurologic O Renal O Vascular O Infection O Valvular O Pulmonary O Unknown O Other

If Deceased, **Date of Death**[10020]**:** mm / dd / yyyy

Hemoglobin[10085]**:** g/dL □ Not Drawn[10086] **Creatinine**[10090]**:** ____ mg/dL □ Not Drawn[10091]

NYHA Classification at Follow-up[10100]**:** O I O II O III O IV

Echocardiogram[10206]**:** O Not Performed O Yes - TTE O Yes - TEE **If** Yes**,** complete the following

Date[10207]**:** mm / dd / yyyy

LVEF[10210]**:** % □ LVEF Not Assessed[10211]

Mitral Regurgitation[10300]**:** O None O Trace/Trivial O 1+ (mild) O 2+ (moderate) O 3+ (moderate – severe) O 4+ (severe)

Note: According to American Society of Echocardiography Guidelines

Effective Orifice Area (EOA) or **EROA** [10315]**:** cm^2 **Method of Assessment**[10320]**:** O 3D Planimetry O PISA O Quantitative Dopplar O Other

Mean Mitral Gradient[10330]**:** mmHg

Left Atrial Volume[10335]**:** mL (OR) **LA Volume Index**[10340]**:** mL/m^2

Left Ventricular Internal Systolic Dimension[10345]**:** cm □ Not Measured[10346]

Left Ventricular Internal Diastolic Dimension[10350]**:** cm □ Not Measured[10351]

Left Ventricular End Systolic Volume[10355]**:** mL □ Not measured[10356]

Left Ventricular End Diastolic Volume[10360]**:** mL □ Not measured[10361]

Tricuspid Regurgitation[10365]**:** O None O Trace/Trivial O Mild O Moderate O Severe

KCCQ-12 Performed[10230]**:** O No O Yes

If Yes, **KCCQ-12**[10231-10243]**:** **Q1a:**____ **Q1b:**____ **Q1c:**____ **Q2:** ___ **Q3:** ___ **Q4:** ___

(See separate questionnaire)

Q5: ___ **Q6:** ___ **Q7:** ___ **Q8a:**____ **Q8b:**____ **Q8c:** ___

Six Minute Walk Test Performed[10380]**:**
O Performed
O Not performed – non-cardiac reason
O Not performed – cardiac reason
O Not performed – patient not willing to walk
O Not performed by site

Test Date[10385]**:** mm / dd / yyyy

Total Distance Walked[10390]**:** _____ ft

I. Follow-Up (cont.) (30 days, 1 Year from date of Procedure)

Adverse Events, Readmissions, Interventions and Surgical Procedures (Specify the event date for each Event that occurred between discharge and 30-day F/U, or between F/U assessment date #1 and F/U assessment date #2.)

Follow-up Events Occurred[10245]**:** O No O Yes **If** Yes, specify the **Event**[10246] **and Event Date(s)**[10247]**:**

Cardiac	**Atrial Fibrillation** (new onset)[E006]**:**	mm / dd / yyyy	Bleeding/Vascular	**Major Vascular Complication**[E041]**:**	mm / dd / yyyy
	Endocarditis[E003]**:**	mm / dd / yyyy		**Minor Vascular Complication**[E042]**:**	mm / dd / yyyy
	Myocardial Infarction[E059]**:**	mm / dd / yyyy		**Major Bleeding Event**[E043]**:**	mm / dd / yyyy
Neuro	**Transient Ischemic Attack**[E010] (complete Adjudication)**:**	mm / dd / yyyy		**Life Threatening Bleeding**[E037]**:**	mm / dd / yyyy
	Ischemic Stroke[E011] (complete Adjudication)**:**	mm / dd / yyyy	Additional Procedures	**Mitral Valve Re-intervention**[E053] (complete Adjudication)**:**	mm / dd / yyyy
	Hemorrhagic Stroke[E012] (complete Adjudication)**:**	mm / dd / yyyy		**ASD Closure Due To Transeptal Catheterization**[E054]**:**	mm / dd / yyyy
	Stroke (Undetermined Type)[E013] (complete Adjudication)**:**	mm / dd / yyyy		**Unplanned Other Cardiac Surgery or Intervention**[E031] (not Mitral)**:**	mm / dd / yyyy
Device	**Device Embolization**[E050]**:**	mm / dd / yyyy		**Unplanned Vascular Surgery or Intervention**[E032] (for Bleeding or Access Site Complication)**:**	mm / dd / yyyy
	Single Leaflet Device Attachment[E049]**:**	mm / dd / yyyy			
	Device Thrombosis[E027]**:**	mm / dd / yyyy			
	Other Device Related Event[E028]**:**	mm / dd / yyyy	Readmission	**Readmission – Heart Failure**[E055] (complete Adjudication)**:**	mm / dd / yyyy
Renal	**New Requirement for Dialysis**[E029]**:**	mm / dd / yyyy		**Readmission – Cardiac** (not HF)[E056]**:**	mm / dd / yyyy
				Readmission – Non-Cardiac (Follow Up)[E057]**:**	mm / dd / yyyy

Follow-Up Medications (medications prescribed or taken at the time of follow-up)

ACE/ARB[10250,10255] (any)**:**	O No O Yes O Contraindicated O Blinded
Beta Blockers[10250,10255] (any)**:**	O No O Yes O Contraindicated O Blinded
Anticoagulants[10250,10255] (any)**:**	O No O Yes O Contraindicated O Blinded
Aspirin[10250,10255] (alone)**:**	O No O Yes O Contraindicated O Blinded
Aspirin (dual antiplatelet therapy)[10250,10255]**:**	O No O Yes O Contraindicated O Blinded
Diuretics – Aldosterone Antagonists[10250,10255]**:**	O No O Yes O Contraindicated O Blinded
Diuretics – Loop[10250,10255]**:**	O No O Yes O Contraindicated O Blinded
If Loop Diuretic, **Dose**[10257]**:** _ mg	
Diuretics (not otherwise specified)[10250,10255]**:**	O No O Yes O Contraindicated O Blinded
Diuretics – Thiazides[10250,10255]**:**	O No O Yes O Contraindicated O Blinded

J. ADJUDICATION FORM (COMPLETE FOR EACH STROKE, TIA, MITRAL VALVE RE-INTERVENTION, OR HEART FAILURE READMISSION)

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

Reference Procedure Start Date[6040]**:** mm / dd / yyyy **Other ID**[2045]**:** **Study Patient ID**[3032]**:** (optional)

Adjudication Event[12000]**:** O Ischemic Stroke(In-hospital) O Hemorrhagic Stroke(In-hospital) O Undetermined Stroke(In-hospital) O TIA(In-hospital)
O Mitral Valve Re-intervention(In-hospital)
O Ischemic Stroke(F-U) O Hemorrhagic Stroke(F-U) O Undetermined Stroke(F-U) O TIA(F-U)
O Mitral Valve Reintervention(F-U)
O Readmission – Heart Failure (F-U)

Event Date[12005]**:** mm / dd / yyyy

Status[12010]**:** O Alive O Deceased **If** Deceased, **Date of Death**[12011]**:** mm / dd / yyyy

IF EVENT[12000] IS STROKE OR TIA

Date of Symptom Onset[12015](approximate)**:** mm / dd / yyyy

Neurologic Deficit with Rapid Onset[12020]**:** O No O Yes

If Yes, **Clinical Presentation**[12025]**:** O Stroke/TIA O Non-Stroke

If Stroke/TIA, **Symptom Duration ≥ 24 hours**[12030]**:** O No O Yes

If Stroke/TIA, **Neuroimaging Performed**[12040]**:** O No O Yes

If Yes, **Deficit Type**[12045]**:** O No deficit O Infarction O Hemorrhage O Both (hem/infarc) O Subarachnoid Hemorrhage

If Stroke/TIA, **Neurologist/Neurosurgeon Confirmation of Diagnosis**[12055]**:** O No O Yes

If Stroke/TIA, **Social/Recreational Activities Impaired**[12056]**:** O No O Yes

If Stroke/TIA, **Neurocognitive Functions Essential to Pt or their Livelihood Impaired:**[12057]**:** O No O Yes **If** Stroke/TIA, **New Aids or Assistance Required:**[12058]**:** O No O Yes

If Stroke/TIA, **Death as a Result of Neurologic Deficit**[12060]**:** O No O Yes

Clinical Comments[12065](information and details that may assist in assessing the stroke or TIA)**:**

IF EVENT[12000] IS MITRAL VALVE RE-INTERVENTION

Mitral Valve Re-intervention Type[12200]**:** O Surgical MV Repair O Surgical MV Replacement O Transcatheter MV Repair
O Transcatheter MV Replacement O Leaflet Clip Procedure O Other Transcath Intervention

If Other Transcatheter Intervention, **Other Type**[12205]**:** _____

MV Reintervention Indication[12210]**:** O Mitral regurgitation O Mitral stenosis O Mitral valve injury
O Device embolization O Endocarditis O Device thrombosis O Other

If Other**, Other Indication**[12215]**:** _____

Clinical Comments[12220](information and details that may assist in assessing this re-intervention)**:**

IF EVENT[12000] IS READMISSION (HEART FAILURE)

Hospitalization >=24 hours[12225]**:** O No O Yes O Information not available

Clinical Signs and/or Symptoms of Heart Failure[12230]**:** O No O Yes O Information not available

IV or Invasive Treatment Required[12335] **:** O No O Yes O Information not available

Note: IV includes diuretics or vasoactive therapy and Invasive includes ultrafiltration, IABP, or mechanical assistance