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

STS/ACC TVT 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	**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]

B. Episode of Care

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]:

C. History and Risk Factors (Patient history and risk factors up to the procedure)

Cardiac History

Infective Endocarditis[4000]: O No O Yes
→**If** Yes, **Infective Endocarditis Type**[4005]: O Treated O Active

Heart Failure Hospitalization w/in Past Year[4006]:
O No O Yes O Not Documented

Permanent Pacemaker[4010]: O No O Yes
→**If** Yes, **CRT**[4013]: O No O Yes

Previous ICD[4015]: O No O Yes
→**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, **AV Replacement – Surgical**[4070]: O No O Yes
→**If** Yes, **AV Repair – Surgical**[4080]: O No O Yes
→**If** Yes, **AV Transcatheter Valve Replacement**[4090]: O No O Yes

Prior Non Aortic Valve Procedure[4095]: O No O Yes
→**If** Yes, **Most Recent MV Procedure Date**[4097]: mm / dd / yyyy
→**If** Yes, **MV Repair – Surgical**[4110]: O No O Yes
→**If** Yes, **Mitral Annuloplasty Ring–Surgical**[4111]:
O No O Yes – partial
O Yes – circumferential O Not Documented

→**If** Yes**, MV Transcatheter Intervention**[4112]: 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, **Prior Tricuspid Valve Repair/Replacement**[4118]: O No O Yes

→**If** Yes, **Prior Pulmonic Valve Repair/Replacement**[4119]: O No O Yes

Other History and Risk Factors

Prior Stroke[4120]: O No O Yes
→**If** Yes, **Most Recent Stroke Date**[4125]: mm / dd / yyyy

Transient Ischemic Attack[4130]: O No O Yes

Carotid Stenosis[4135]: O None O Right O Left O Both O NA
→**If** Yes, **Prior CEA/CAS**[4140]: O No O Yes

Peripheral Arterial Disease[4145]: O No O Yes

Current Smoker[4150] (w/in 1 year): O No O Yes

Hypertension[4155]: O No O Yes

Diabetes Mellitus[4165]: O No O Yes
→**If** Yes, **Diabetes Therapy**[4170]:
O None O Diet O Oral O Insulin O Other

Currently on Dialysis[4175]: O No O Yes

Chronic Lung Disease[4180]: O None O Mild O Moderate O Severe

Home Oxygen[4181]: O No O Yes

Hostile Chest[4182]: 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 →**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	
Porcelain Aorta[5045]:		O No	O Yes	O Not performed – non-cardiac reason	
Atrial Fibrillation/Flutter[5050]:		O No	O Yes	O Not performed – cardiac reason	
→**If** Yes, **AF Class w/in past 30 days**[5052]: O None O Persistent O Paroxysmal				O Not performed – patient not willing to walk	
				O Not performed by site	
				Test Date[5116]: mm / dd / yyyy	
				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) [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) [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)[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	Readmission	**Readmission – Heart Failure**[E055] (complete Adjudication): mm / dd / yyyy
	Device Thrombosis[E027]:	mm / dd / yyyy		**Readmission – Cardiac** (not HF)[E056]: mm / dd / yyyy
	Other Device Related Event[E028]:	mm / dd / yyyy		**Readmission – Non-Cardiac** (Follow Up)[E057]: mm / dd / yyyy
Renal	**New Requirement for Dialysis**[E029]:	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

PRA Disclosure Statement

*According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1202 (Expires 12/31/2020). The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. ****CMS Disclosure**** **Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact Sarah Fulton at sarah.fulton@cms.hhs.gov.***

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