Mitral Valve in Valve **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 Replacement – Surgical**[4100]: O No O Yes
→**If** Yes, **MV Type**[4105]:
O Bioprosthetic stented
O Bioprosthetic stentless
O Not Documented
→**If** Yes, **MV Replacement Model ID**[4106]: Refer to Device List

→**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 Coronary sinus based intervention
O Valve-in-Valve
O Direct annuloplasty intervention
O Valve-in-native Valve
O Other

Mitral Valve or Ring Model ID[4116]: Refer to Device List

→**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

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

OTHER HISTORY AND RISK FACTORS

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 →**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	
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	
→**If** Yes, **AF Class w/in past 30 days**[5052]**:** O None O Persistent O Paroxysmal			**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)

→**If** Prior MV Replacement, **Paravalvular Severity**[5696]**:** O None O Mild O Moderate O Severe O Not Documented

→**If** Prior MV Replacement, **Valvular Severity**[5697]**:** O None O Mild O Moderate O Severe O Not Documented

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

MV 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

→**If** Prior Prosthetic MV, **Prosthetic Mitral Valve Dysfunction Etiology**[5742]:

O Primary/degenerative bioprosthetic Valve Failure O Pannus formation O Thrombus formation O Other

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 (CONT.)

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

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

E. PROCEDURE INFORMATION (COMPLETE FOR EACH MITRAL VALVE-IN-VALVE OR VALVE-IN-RING 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/Time[6040,6041]**:** mm / dd / yyyy HH:MM **Procedure Stop Date/Time**[6045,6046]**:** mm / dd / yyyy HH:MM

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

Operator Reason for Procedure[29115]**:**
O Inoperable/Extreme risk (technically inoperable, co-morbid or deconditioned patient)
O High risk (>=8% risk of 30 day mortality)
O Intermediate risk (4-7% risk of 30 day mortality)
O Low risk (<4% risk of 30 day mortality)

Procedure Aborted[29120]**:** O No O Yes

→**If** Yes, **Reason**[29125]**:** O Access related O Navigation issue after successful access
O New clinical findings O Device/delivery system malfunction
O Patient clinical status O Consent issue
O Transseptal access related O System issue
O Other (not specified)

→**If** Yes, **Action**[29127]**:** O Balloon valvuloplasty O Rescheduled transcatheter procedure
O Conversion to open heart surgery O Converted to medical therapy
O Converted to clinical trial O Open heart surgery scheduled O Other

Conversion to Open Heart Surgery[29130]**:** O No O Yes

→**If** Yes, **Reason**[29135]**:** O Access related problem/injury O Inability to position device O Valve injury
O Device embolization O Tamponade/bleeding in the heart O Other

Mechanical Assist Device[29140]**:** O No O Yes

→**If** Yes, **Timing**[29145]**:** O Pre-procedure O Intraprocedure O Postprocedure

→**If** Yes, **Type**[29146]**:** O IABP O Catheter-based assist device

Procedure Access Site[29180]**:** O Transseptal O Transapical O Direct left atrium O Femoral artery O Other

CardioPulmonary Bypass Used[6100]**:** O No O Yes →**If** Yes, **Status**[6101]**:** O Elective O Emergent

→**If** Yes, **CPB Time** [6105]**:** _____ mins

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

Pre-Implant Balloon Inflation Performed[29185]**:** O No O Yes

→**If** Yes, **Significant Hemodynamic Deterioration After Inflation**[29190]**:** O No O Yes

PROSTHETIC VALVE/DEVICE INVENTORY

Device 1 Used[29201]: Refer to Device List **Device Serial Number**[29205]: _____

Device 2 Used[29201]: Refer to Device List **Device Implanted Successfully**[29225]: O No O Yes

UDI[29210, 29215, 29220]: (future) **Post-Implant Balloon Inflation Performed**[29195]: O No O Yes

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[29290](highest): _____ mmHg

Contrast Volume[29295]: _____ ml

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

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]:	Neuro	**Transient Ischemic Attack**[E010] (complete Adjudication):
	Cardiac Arrest[E005]:		**Ischemic Stroke**[E011](complete Adjudication):
	Conduction/Native Pacer Disturbance Req Pacer[E039]:		**Hemorrhagic Stroke**[E012] (complete Adjudication):
	Conduction/Native Pacer Disturbance Req ICD[E040]:		**Stroke (Undetermined Type)**[E013] (complete Adjudication):
	Endocarditis[E003]:	Bleed/Vascular	**Bleeding at Access Site**[E017]:
	LVOT Obstruction[E044]:		**Hematoma at Access Site**[E018]:
	Myocardial Infarction[E059]:		**Retroperitoneal Bleeding**[E019]:
	Perforation w/ or w/o Tamponade[E009]:		**GI Bleed**[E020]:
Device	**Device Embolization**[E050]:		**GU Bleed**[E021]:
	Device Recapture or Retrieval[E026]:		**Other Bleed**[E022]:
	Device Thrombosis[E027]:		**Transapical Related Event**[E014]:
	Device Migration[E023]:		**Transseptal Related Event**[E052]:
	Other Device Related Event[E028]:		**Major Vascular Complication**[E041]:
Renal	**New Requirement for Dialysis**[E029]:		**Minor Vascular Complication**[E042]:
		Additional Procedures	**ASD Closure Due To Transseptal Catheterization**[E054]:
			Mitral Valve Re-intervention[E053] (complete Adjudication):
			Unplanned Vascular Surgery or Intervention[E032] (for Bleeding or Access Site Complication):
			Unplanned Other Cardiac Surgery or Intervention[E031] (not MVR):

All dates: 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]

12-Lead ECG Findings[8060]**:** O Not performed O No significant changes O New pathological Q-wave or LBBB

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

→**If** Trace/Trivial, Mild, Moderate, or Severe, **Paravalvular Severity**[8112]**:** O None O Mild O Moderate O Severe O Not Documented

→**If** Trace/Trivial, Mild, Moderate, or Severe, **Valvular Severity**[8115]**:** O None O Mild O Moderate O Severe O Not Documented

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](highest)**:** _____ mmHg

LVOT gradient (peak)[8140]**:** _____ mmHg **Mitral Valve Area**[8135]**:** _____ cm^2

Systolic Anterior Motion Present[8145]**:** O No O Yes

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

→**If** Trace/Trivial, Mild, Moderate, or Severe, **Paravalvular Severity**[10305]: O None O Mild O Moderate O Severe O Not Documented

→**If** Trace/Trivial, Mild, Moderate, or Severe, **Valvular Severity**[10310]: O None O Mild O Moderate O Severe O Not Documented

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

Mitral Valve Area[10325]: _____ cm^2 **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

LVOT gradient (peak)[10370]: _____mmHg

Systolic Anterior Motion Present[10375]: O No O Yes

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
	Conduction/Native Pacer Disturbance Req Pacer[E039]:	mm / dd / yyyy		**Minor Vascular Complication**[E042]:	mm / dd / yyyy
	Conduction/Native Pacer Disturbance Req ICD[E040]:	mm / dd / yyyy		**Transapical Related Event**[E014]:	mm / dd / yyyy
	Endocarditis[E003]:	mm / dd / yyyy		**Major Bleeding Event**[E043]:	mm / dd / yyyy
	Myocardial Infarction[E059]:	mm / dd / yyyy		**Life Threatening Bleeding**[E037]:	mm / dd / yyyy
Neuro	**Transient Ischemic Attack**[E010] (complete Adjudication):	mm / dd / yyyy	Additional Procedures	**Mitral Valve Re-intervention**[E053] (complete Adjudication):	mm / dd / yyyy
	Ischemic Stroke[E011] (complete Adjudication):	mm / dd / yyyy		**ASD Closure Due To Transeptal Catheterization**[E054]:	mm / dd / yyyy
	Hemorrhagic Stroke[E012] (complete Adjudication):	mm / dd / yyyy		**Unplanned Other Cardiac Surgery or Intervention**[E031] (not Mitral):	mm / dd / yyyy
	Stroke (Undetermined Type)[E013] (complete Adjudication):	mm / dd / yyyy		**Unplanned Vascular Surgery or Intervention**[E032] (for Bleeding or Access Site Complication):	mm / dd / yyyy
Device	**Device Embolization**[E050]:	mm / dd / yyyy	Readmission	**Readmission – Heart Failure**[E055] (complete Adjudication):	mm / dd / yyyy
	Device Fracture[E038]:	mm / dd / yyyy		**Readmission – Cardiac** (not HF)[E056]:	mm / dd / yyyy
	Device Migration[E023]:	mm / dd / yyyy		**Readmission – Non-Cardiac** (Follow Up)[E057]:	mm / dd / yyyy
	Device Thrombosis[E027]:	mm / dd / yyyy			
	Other Device Related Event[E028]:	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]: ____ mg	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]:				
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

Mitral Valve in Valve **Data Collection Form v2.1**

STS/ACC TVT Registry™

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