Transcatheter Mitral Leaflet Clip Procedure (TMVr)
v3 Data Collection Form

STS/ACC TVT Registry™

A. Demographics

Last Name[2000]:	**First Name**[2010]:	**Middle Name**[2020]:
Birth Date[2050]: mm / dd / yyyy	**SSN**[2030]: - - ☐ SSN N/A[2031]	**Patient ID**[2040]: (auto)
Other ID[2045]:	**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] ☐ Native Hawaiian/Pacific Islander[2074] ☐ Middle Eastern/North African[2075]

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

B. Episode of Care

Arrival Date/Time[3001]: mm / dd / yyyy / hh:mm

Admitting Provider's Name, NPI[3050,3051,3052,3053]: _____ *Last Name, First Name, MI, NPI*

Attending Provider's Name, NPI[3055,3056,3057,3058]: _____ *Last Name, First Name, MI, NPI*, _____ *Last Name, First Name, MI, NPI*

Health Insurance[3005]: O No O Yes

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

MBI #[12846]:

Residence[13803]: O Home with No Health Aid O Home with Health Aid O Long Term Care O Other ☐ Not Documented[13804]

Research Study

Patient Enrolled in Research Study[3020]: O No O Yes ☐ **Patient Restriction**[3035]

→ If Yes, **Research Study Name**[3025], **Research Study Patient ID**[3030]: _____, _____

Transcatheter Valve Therapy (TVT) Pathway

TVT Pathway[13171]: ☐ TAVR ☐ TMVr ☐ TMVR ☐ Tricuspid Valve Procedure

Basic dataset

C. History and Risk Factors

Height[6000]: _____ cm **Weight**[6005]: _____ kg

Number of Prior Open Heart Cardiac Surgeries[13697]: ___ *(If the patient has had >4 prior surgeries and the number is not known, code 4 prior surgeries)*

Heart Failure Hospitalization Within Past Year[13707]: O No O Yes □ Not Documented[14253]

Oxygen at Home[13881]: O No O Yes

Immunocompromise Present[13882]: O No O Yes **Currently on Dialysis**[13880] O No O Yes

Tobacco Use[4625]: O Never O Former O Current-Every Day O Current-Some Days O Smoker – Current Status Unk O Unk if ever smoked

→If any Current, **Tobacco Type**[4626] *(Select all that apply)*: ☐ Cigarettes ☐ Cigars ☐ Pipe ☐ Smokeless

→If Current Every Day and Cigarettes, **Amount**[4627]: O Light tobacco use (<10/day) O Heavy tobacco use (>=10/day)

Home Medications

Category	Medication Code[12297]	Med Prescribed[13903]	Loop Diuretic Dose[14575]
ACE Inhibitors (Angiotensin Converting Enzyme)	**Angiotensin Converting Enzyme Inhibitor**	O No O Yes	
Aldosterone Antagonist	**Aldosterone Antagonist**	O No O Yes	
Angiotensin Receptor-Neprilysin Inhibitor	**Angiotensin Receptor-Neprilysin Inhibitor**	O No O Yes	
Anticoagulant	**Anticoagulant**	O No O Yes	
Antiplatelet	**Aspirin**	O No O Yes	
ARB (Angiotensin Receptors Blockers)	**Angiotensin II Receptor Blocker**	O No O Yes	
Beta Blockers	**Beta Blocker**	O No O Yes	
Diuretics	**Diuretics Not Otherwise Specified**	O No O Yes	
	Loop Diuretics	O No O Yes	_____ mg
	Thiazides	O No O Yes	
P2Y12 Inhibitors	**P2Y12 Antagonist**	O No O Yes	
Selective Sinus Node I/f Channel Inhibitor	**Selective Sinus Node I/f Channel Inhibitor**	O No O Yes	

Condition and Procedure History Information (Patient History and Risk Factors up to the Procedure)

Condition History[12903]	Occurrence[14264] No	Occurrence[14264] Yes	Date[14251]	
Atrial Fibrillation	O	O		→**If Yes, AFib Class**[13179]: O Paroxysmal O Persistent O Long-standing Persistent (w/in 30 days) O Permanent O None →**If Parox or persis, Recent AF** (w/in 30 days)[14244]: O No O Yes
Atrial Flutter	O	O		→**If Yes, Recent Aflutter** (w/in 30 days)[14245]: O No O Yes
Cardiomyopathy	O	O		→ **If Yes, CM Type**[4570]: ☐ Ischemic ☐ Non-ischemic ☐ Other
Carotid Artery Stenosis	O	O		→ **If Yes, Current Carotid Artery Stenosis**[14265]: O No O Yes → **If Yes, Location**[14230]: O Right O Left O Bilateral ☐ Location Not Documented[14329]
Cerebrovascular Accident (any)	O	O	mm/dd/yyyy	
Cerebrovascular Disease	O	O		
Chronic Lung Disease	O	O		→ **If Yes, Severity**[13904]: O Mild O Moderate O Severe ☐ Severity Not Documented[14459]
COVID-19	O	O		
Dementia - Moderate to Severe	O	O		
Diabetes Mellitus	O	O		→ **If Yes, Therapy**[14231]: O None O Diet O Oral O Insulin O Other
Endocarditis	O	O		→ **If Yes, Type**[14232]: O Treated O Active
Heart Failure	O	O		
Hostile Chest	O	O		
Hypertension	O	O		
Liver Disease	O	O		
Myocardial Infarction	O	O		→**If Yes, MI Timeframe**[13174]: O <30 days O >=30 days
Peripheral Arterial Disease	O	O		
Porcelain Aorta	O	O		
Transient Ischemic Attack	O	O		

Procedure History[12905]	Occurrence[14268] No	Occurrence[14268] Yes	Date[14252]	
Aortic Valve Procedure	O	O	mm/dd/yyyy	
Aortic Valve Repair Surgery	O	O		
Aortic Valve Replacement Surgery	O	O		
Aortic Valve Replacement - Transcatheter	O	O		
Coronary Artery Bypass Graft	O	O	mm/dd/yyyy	
Implantable Cardioverter Defibrillator	O	O		→ **If Yes, CRT-D**[14259]: O No O Yes
Mitral Valve Procedure	O	O	mm/dd/yyyy	
Mitral Valve Annuloplasty Ring Surgery	O	O		→ **If Yes, MV Ring Type**[14257]: O Partial O Circumferential ☐ Not Documented[14258]
Mitral Valve Repair Surgery	O	O		
Mitral Valve Replacement Surgery	O	O		
Mitral Valve Transcathter Intervention	O	O		→ **If Yes, Type**[14261]: O Leaflet Clip O Direct Annuloplasty Intervention O Coronary Sinus Based Intervention O Valve-in-Native Valve O Valve-in-Valve O Other
PCI	O	O	mm/dd/yyyy	
Permanent Pacemaker	O	O	mm/dd/yyyy	→ **If Yes, CRT**[14260] O No O Yes
Pulmonic Valve Procedure	O	O		
Tricuspid Valve Procedure	O	O	mm/dd/yyyy	

D. Lab Visit (Complete For Each Lab Visit)

Procedures[14273]: □ TAVR □ TMVr □ TMVR □ Tricuspid Valve Procedure

→**If** Mitral Repair, **Mitral Leaflet Clip**[13793] O No O Yes

Procedure Room Entry Date/Time[13329]: mm / dd / yyyy HH:MM **Procedure Start Date/Time**[7000]: mm / dd / yyyy HH:MM

Procedure End Date/Time[7005]: mm / dd / yyyy HH:MM **Procedure Room Exit Date/Time**[13330]: mm / dd / yyyy HH:MM

Presentation and Evaluation

CAD Presentation[12177]: O No Symptoms, No Angina O Symptoms Unlikely to be Ischemic O Stable Angina O Unstable Angina O Non-STEMI O STEMI

Heart Failure (w/in 2 weeks)[14266]: O No O Yes

NYHA Class (w/in 2 weeks)[12163]: O I O II O III O IV

Cardiogenic Shock (w/in 24 hrs)[13175]: O No O Yes

Cardiac Arrest (w/in 24 hrs)[14267]: O No O Yes

STS Risk Score Type [13698]: **STS Risk Score Measurement**[14271]:
MV Repair: _____ %
MV Replace: _____ %

Shared Decision Making[14732]: O No O Yes

→**If** Yes, **Shared Decision Making Tool Used**[14733]: O No O Yes →**If** Yes, **Shared Decision Making Tool Name**[14734]: _____

KCCQ-12 Performed[13843]: O No O Yes

→**If** Yes, **KCCQ-12**[13846, 48, 49, 51, 53, 55, 57, 59, 61, 63, 65, 67] (see separate questionnaire) **Q1a:** _____ **Q1b:** _____ **Q1c:** _____ **Q2:** _____ **Q3:** _____ **Q4:** _____

Q5: _____ **Q6:** _____ **Q7:** _____ **Q8a:**_____ **Q8b:**_____ **Q8c:**_____ **KCCQ Summary Score**[14310] **(calculated)** _____

Six Minute Walk Test[13710]: O No O Yes →**If** Yes, **Test Date**[13711]: mm / dd / yyyy →**If** Yes, **Total Distance**[13712]: _____ ft

→**If** No, **Reason**[14262]: O Non-Cardiac Reason O Cardiac Reason O Patient Not Willing to Walk O Not Performed By Site

Pre-Procedure Clinical Data (Closest to the Procedure)

Hemoglobin[6030]: _____ g/dL □ Not Drawn[6031]

Sodium[6035]: _____ mEq/L □ Not Drawn[6036]

Creatinine[6050]: _____ mg/dL □ Not Drawn[6051]

BNP[14280]: _____ pg/mL □ Not Performed[13205]

(or)

NT proBNP[14279]: _____ pg/mL □ Not Performed[13206]

Pre-Procedure ECG and Pulmonary Function (Closest to the Procedure)

QRS Duration[5055]: _____ msec □ Ventricular Paced[5045]

FEV1 Predicted[13216]: _____ % □ Not Performed[13217]

DLCO (Predicted)[13218]: _____ % □ Not Performed[13219]

Pre-Procedure Medications (24 hours prior to the procedure)

Positive Inotropes[13643]: O No O Yes

Pre-Procedure Diagnostic Cath Findings

Diagnostic Cath Performed[13220]: O No O Yes → **If** Yes, **Diagnostic Cath Date**[13222]: mm / dd / yyyy

Number of Diseased Vessels[13381]: O None O One O Two O Three □ Not Documented[13382]

Left Main Stenosis >=50%[13260]: O No O Yes □ Not Documented[13261]

Proximal LAD >=70%[13301]: O No O Yes □ Not Documented[13302]

Cardiac Output[13713]: _____ L/min □ Not Documented[13714]

Pulmonary Capillary Wedge Pressure[13715]: _____ mm Hg □ Not Documented[13716]

Pulmonary Artery Pressure (mean)[13719]: _____ mm Hg □ Not Documented[13720]

Pulmonary Artery Pressure (systolic)[13717]: _____ mm Hg □ Not Documented[13718]

Right Atrial Pressure (mean)[14272]: _____ mm Hg □ Not Documented[13829]

PRE-PROCEDURE ECHOCARDIOGRAM FINDINGS

LVEF[13305]: _____ % □ LVEF Not Assessed[13306]

Left Ventricular Internal Systolic Dimension[13721]: _____ cm □ Not Measured[13722]

Left Ventricular Internal Diastolic Dimension[13723]: _____ cm □ Not Measured[13724]

Left Ventricular End Systolic Volume[13725]: _____ mL □ Not Measured[13727]

Left Ventricular End Diastolic Volume[13726]: _____ mL □ Not Measured[13728]

Left Atrial Volume[13729]: _____mL □ Not Measured[13730] (OR) **LA Volume Index**[13731]: _____mL/m^2 □ Not Measured[13732]

Aortic Regurgitation[13477]: (highest) O None O Trace/Trivial O Mild O Moderate O Severe

Aortic Stenosis[13307]: O No O Yes

Mitral Valve Disease[13704]: O No O Yes

→**If** Yes, **Mitral Regurgitation**[13672]: (highest) O None O Trace/Trivial O Mild O Moderate O Moderate-Severe O Severe

→**If** Yes, **Effective Regurgitant Orifice Area (EROA)**[13737]:_____ cm^2 →**If** EROA, **Method of Assessment**[13738]: O 3D Planimetry O PISA O Quantitative Dopplar O Other

→**If** Yes, **Mitral Stenosis**[13308]: O No O Yes

→**If** Yes, **MV Area**[13316]: (smallest) _____ cm^2 *(required only if mitral stenosis=yes)*

→**If** Yes, **MV Mean Gradient**[13317]: (highest) _____ mm Hg *(required only if mitral stenosis=yes)*

Mitral Valve Disease Etiology[13490] (*Check all that apply*): O Functional MR (Secondary) O Degenerative MR (Primary) O Post Inflammatory O Endocarditis O Other O None

→**If** Functional, **Functional Type**[13740]: 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) □ Not Documented[13741]

→**If** Degenerative, **Leaflet Prolapse**[13742]:O None O Anterior O Posterior O Bileaflet □ Not Documented[13745]

→**If** Degenerative, **Leaflet Flail**[13743]: O None O Anterior O Posterior O Bileaflet □ Not Documented[13746]

→**If** Inflammatory, **Type**[13748]: O Collagen Vascular Disease O Drug Induced O Idiopathic O Prior Radiation Therapy O Rheumatic Fever □ Not Documented[13753]

Leaflet Tethering[13744]: O None O Anterior O Posterior O Bileaflet □ Not Documented[13747]

Mitral Valve Annular Calcification[13749]: O No O Yes □ Not Documented[13750]

Mitral Leaflet Calcification[13751]: O Yes O No □ Not Documented[13752]

Tricuspid Regurgitation[13318]: (highest) O None O Trace/Trivial O Mild O Moderate O Severe

PROCEDURE INFORMATION

Concomitant Procedures Performed[7065]: O No O Yes

→**If** Yes, **Procedure Type(s)**[7066]: (select the best option(s)): _____, _____, _____

Operator Name/NPI[14476, 14477, 14478, 14479]: *Last Name, First Name, MI, NPI* _____, *Last Name, First Name, MI, NPI* _____

Procedure Status[7025]: O Elective O Urgent O Emergency O Salvage

Procedure Location[12871]: O Cardiac CathLab O Hybrid CathLab Suite OHybrid OR Suite O Other

Anesthesia Type[13331]: O General Anesthesia O Deep sedation/Analgesia O Moderate Sedation/Analgesia O Minimal Sedation/Anxiolysis

Procedure Aborted[13505]: O No O Yes

→**If** Yes, **Reason**[13506]: O Access Related O Consent Issue O Device Delivery System Malfunction O Navigation Issue After Successful Access O New Clinical Findings O Patient Clinical Status O System Issue O Transseptal Access Related O Other

→**If** Yes, **Action**[13757]: O Conversion to Open Heart Surgery O Scheduled Open Heart Surgery O Rescheduled Transcatheter Procedure O Converted to Clinical Trial O Balloon Valvuloplasty O Converted to Medical Therapy O Other

PROCEDURE INFORMATION (CONT.)

Conversion to Open Heart Surgery[13542]: O No O Yes

→**If** Yes, **Reason**[13543]: O Access Related O Cardiac Tamponade O Inability to Position Device O Device Embolization O Valve Injury O Other

Mechanical Support[7422]: O No O Yes →**If** Yes, **Device**[7423]: _____

→**If** Yes, **Timing**[7424]: O In place at start of procedure O Inserted during procedure and prior to intervention O Inserted after intervention has begun O Post Procedure

CardioPulmonary Bypass Used[13579]: O No O Yes

→**If** Yes, **Status**[13580]: O Elective O Emergency →**If** Yes, **CPB Time**[13581]: _____ min

PROCEDURE MEDICATIONS (DURING THE PROCEDURE)

Positive Inotropes[13644] O No O Yes

RADIATION AND CONTRAST

CODE ALL AVAILABLE MEASUREMENTS

Dose Area Product[14278]: _____ O Gy · cm^2 O dGy · cm^2 O cGy · cm^2 O mGy · cm^2 O µGy · M^2

Cumulative Air Kerma[7210]: _____ O mGy O Gy **Fluoro Time**[7214]: _____ min **Contrast Volume**[7215]: _____ mL

POST IMPLANT MITRAL VALVE DATA

MV Gradient (mean)[13762] *(post implant)*: _____ mm Hg

Mitral Regurgitation[14274] *(post implant)*: O None O Trace/Trivial O Mild O Moderate O Severe

TMVr PROCEDURE INFORMATION - INDICATIONS FOR MITRAL LEAFLET CLIP PROCEDURE

Mitral Leaflet Clip Procedure Indication *(Check all that apply)*[13792]:

- □ Refractory to Guideline Determined Optimal Medical Therapy
- □ Frailty
- □ Hostile Chest
- □ Severe Pulmonary Hypertension
- □ Severe Liver Disease (Cirrhosis or MELD score >12)
- □ Porcelain Aorta *(or extensively calcified ascending aorta)*
- □ Predicted STS MV Repair Operative Mortality Risk of >=6% *(for patients deemed likely to undergo MV repair)*
- □ Predicted STS MV Replacement Operative Mort Risk >=8% *(for patients deemed likely to undergo MV replacement)*
- □ Right Ventricular Dysfunction w/Severe Tricuspid Regurg
- □ Major Bleeding Diathesis
- □ Chemotherapy for Malignancy
- □ AIDS
- □ Immobility
- □ High Risk of Aspiration
- □ Severe Dementia
- □ IMA at High Risk of Injury
- □ Other

TMVr PROCEDURE INFORMATION

Guiding Cath Access Site[13794]: O Right Femoral Vein O Left Femoral Vein O Jugular Vein O Other Vein

Steerable Guide Cath Device ID[13795]: _____ **Steerable Guide Cath Serial Number**[13796]: _____

→**If** Procedure Aborted is No, **TMVr DEVICES**	**DEVICE 1**[13533]	**DEVICE 2**[13533]
Device ID[13797]:	Refer to Device List	Refer to Device List
Location[13800]:	O A1P1 O A2P2 O A3P3 O Other	O A1P1 OA2P2 O A3P3 O Other
Device Implanted Successfully[13799]:	O No O Yes	O No O Yes
→**If** Yes, **Device Serial #**[13798]:		
→**If** Yes, **UDI**[14574]:		
→**If** Yes, **Deployed Then Removed**[13802]:	O No O Yes	O No O Yes
→**If** No, **Reason**[13801]:	O Adverse Event O Device Malfunction O Inability to Grasp Leaflets O Inability to Reduce MR O MV Injury O Mitral Stenosis O Other	O Adverse Event O Device Malfunction O Inability to Grasp Leaflets O Inability to Reduce MR O MV Injury O Mitral Stenosis O Other

POST-PROCEDURE - INTRA OR POST-PROCEDURE EVENTS (COMPLETE FOR EACH PROCEDURE TYPE AND EVERY OCCURRENCE)

INTRA OR POST PROCEDURE EVENT(S)[12153]	EVENT(S) OCCURRED[9002]	→ IF YES, EVENT DATE(S)[14275]
ASD Defect Closure due to Transseptal Catheterization	O No O Yes	mm / dd / yyyy
Atrial Fibrillation	O No O Yes	mm / dd / yyyy
Bleeding – Access Site	O No O Yes	mm / dd / yyyy
Bleeding – Gastrointestinal	O No O Yes	mm / dd / yyyy
Bleeding – Genitourinary	O No O Yes	mm / dd / yyyy
Bleeding – Other	O No O Yes	mm / dd / yyyy
Bleeding - Hematoma at Access Site	O No O Yes	mm / dd / yyyy
Bleeding – Retroperitoneal	O No O Yes	mm / dd / yyyy
Cardiac Arrest	O No O Yes	mm / dd / yyyy
Cardiac Perforation	O No O Yes	mm / dd / yyyy
Cardiac Surgery or Intervention – Other Unplanned	O No O Yes	mm / dd / yyyy
Complete Leaflet Clip Detachment	O No O Yes	mm / dd / yyyy
Delivery System Component Embolization	O No O Yes	mm / dd / yyyy
COVID19	O No O Yes	mm / dd / yyyy
Device Embolization	O No O Yes	mm / dd / yyyy
Device Thrombosis	O No O Yes	mm / dd / yyyy
Device Related Event – Other	O No O Yes	mm / dd / yyyy
Dialysis (New Requirement)	O No O Yes	mm / dd / yyyy
Endocarditis	O No O Yes	mm / dd / yyyy
Mitral Leaflet or Subvalvular Injury	O No O Yes	mm / dd / yyyy
Myocardial Infarction	O No O Yes	mm / dd / yyyy
Permanent Pacemaker	O No O Yes	mm / dd / yyyy
Reintervention – Mitral Valve (complete event info)	O No O Yes	mm / dd / yyyy
Single Leaflet Device Attachment	O No O Yes	mm / dd / yyyy
Stroke – Ischemic (complete event info)	O No O Yes	mm / dd / yyyy
Stroke – Hemorrhagic (complete event info)	O No O Yes	mm / dd / yyyy
Stroke – Undetermined (complete event info)	**O No O Yes**	mm / dd / yyyy
Transient Ischemic Attack (TIA) (complete event info)	O No O Yes	mm / dd / yyyy
Transseptal Complication	O No O Yes	mm / dd / yyyy
Vascular Complication – Major	O No O Yes	mm / dd / yyyy
Vascular Complication – Minor	O No O Yes	mm / dd / yyyy
Vascular Surgery or Intervention – Unplanned	O No O Yes	mm / dd / yyyy

IN-HOSPITAL EVENT INFORMATION (COMPLETE FOR EACH ISCHEMIC, HEMORRHAGIC, UNDETERMINED STROKE, TIA OR MV RE-INTERVENTION)

Event[14312]: **Event Date**[14313]: mm / dd / yyyy

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)

Status[14314]: O Alive O Deceased →**If** Deceased, **Date of Death:**[14315]: mm / dd / yyyy

Clinical Comments[14462]:

→IF EVENT[14312] = STROKE OR TIA (IN-HOSPITAL)

Symptom Onset Date[14316]: mm / dd / yyyy

Neurologic Deficit with Rapid Onset[14317]: O No O Yes

→**If** Yes, **Clinical Presentation**[14318]: O Stroke/TIA O Non-Stroke

→**If** Stroke/TIA, **Symptom Duration ≥ 24 hours**[14319]: O No O Yes

→**If** Stroke/TIA, **Brain Imaging Performed**[14320]: O No O Yes

→**If** Yes, **Brain Imaging Type**[14349]: O CT O CT w/Contrast O MRI O MRI w/Contrast O Other (e.g. angiography)

→**If** Yes, **Brain Imaging Findings**[14350]: O Infarct O Hemorrhage O No Deficit

→**If** Stroke/TIA, **Event Related Sequelae**[14351] *(Select all that apply)*:
☐ Death ☐ Permanent Vegetative State
☐ Altered Consciousness ☐ Blindness ☐ Aphasia ☐ Loss of Motor Function
☐ Loss of Sensory Function ☐ Facial Paralysis ☐ Prolonged Length of Stay ☐ Other

→**If** Status=Alive, **Discharge Location**[14352]: O Home O Skilled Nursing Facility O Extended Care/TCU/Rehab O Other Discharge Location

→**If** Status=Alive, **Patient Discharged to Prior Place of Living**[14421]: O No O Yes

→**If** Status=Deceased, **Stroke Diagnosed During Autopsy**[14353]: O No O Yes O Info Not Available

→IF EVENT[14312] = MITRAL VALVE RE-INTERVENTION (IN-HOSPITAL)

Mitral Valve Re-intervention Type[14360]:
O Surgical Replacement O Surgical Repair O Transcatheter Replacement
O Balloon Valvuloplasty O Leaflet Clip Procedure O Paravalvular Leak Closure
O Other Transcatheter Intervention

MV Re-intervention Indication[14361]:
O Regurgitation O Stenosis O Device Embolization
O Endocarditis O Device Thrombosis O Valve Injury O Other

POST-PROCEDURE LABS AND ECG (COMPLETE FOR EACH PROCEDURE TYPE)

Hemoglobin (lowest)[13763]: _____ (g/dL) ☐ Not Drawn[14243] **Creatinine (highest)**[13764]: _____ (mg/dL) ☐ Not Drawn[14293]

12-Lead ECG Performed[13616]: O No O Yes

→**If** Yes, **12-Lead ECG Findings**[13765] *(Check all that apply)*: ☐ No Significant Changes ☐ Pathological Q Wave ☐ New LBBB ☐ Cardiac Arrhythmia

POST-PROCEDURE ECHOCARDIOGRAM *(COMPLETE FOR EACH PROCEDURE)*

Echocardiogram[13592]: O Yes – TTE O Yes - TEE ☐ Not Performed[13645] →**If** Yes, **Date**[13493]: mm / dd / yyyy

→**If** Yes, **Mitral Regurgitation** (highest)[13494]: O None O Trace/Trivial O Mild O Moderate O Moderate-Severe O Severe

→**If** Yes, **Effective Regurgitant Orifice Area (EROA)**[13779]: _____ cm^2 →**If** EROA, **Method of Assessment**[13769]: O 3D Planimetry O PISA O Quantitative Dopplar O Other

→**If** Yes, **MV Mean Gradient**[13770]: (highest) _____ mm Hg

E. DISCHARGE

Discharge Date[10100]: mm / dd / yyyy

Discharge Provider Name, NPI[10070,10072,10071,10073]: *Last Name, First Name, MI, NPI*

Discharge Status[10105] O Alive O Deceased

→ **If** Alive, **Cardiac Rehabilitation Referral**[10116]: O No - Reason Not Documented O No - Medical Reason Documented O No - Health Care System Reason Documented O No - Patient-Oriented Reason O Yes

→ **If** Alive, **Discharge Location**[10110]: O Home O Skilled Nursing Facility O Extended Care/TCU/Rehab O Other Acute Care Hospital O Left Against Medical Advice (AMA) O Other Discharge Location

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

→ **If** Deceased, **Death During 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

PRBCs Transfused[9275]: O No O Yes *Note: Code the total # of units between start of the procedure and discharge*

→**If** Yes, **PRBCs Units Transfused**[13670]: _____

DISCHARGE MEDICATIONS *D/c meds are not required for patients who expired, discharged to "Other Acute Care Hospital," "AMA", or are receiving Hospice Care.*

CATEGORY	MEDICATION CODE[10200]	PRESCRIBED[10205]				→ If Yes, LOOP DIURETIC DOSE[14576]
		YES	NO– NO REASON	NO– MEDICAL REASON	NO– PT REASON	
ACE Inhibitors (Angiotensin Converting Enzyme)	Angiotensin Converting Enzyme Inhibitor	O	O	O	O	
Aldosterone Antagonist	Aldosterone Antagonist	O	O	O	O	
Anticoagulant	Direct Thrombin Inhibitor	O	O	O	O	
	Warfarin	O	O	O	O	
Antiplatelet	Aspirin	O	O	O	O	
ARB (Angiotensin Receptors Blockers)	Angiotensin II Receptor Blocker	O	O	O	O	
Beta Blockers	Beta Blocker	O	O	O	O	
Diuretics	Diuretics Not Otherwise Specified	O	O	O	O	
	Loop Diuretics	O	O	O	O	_____ mg
	Thiazides	O	O	O	O	
Non-Vitamin K Dependent Oral Anticoagulant	Direct Factor Xa Inhibitor	O	O	O	O	
P2Y12 Inhibitors	P2Y12 Antagonist	O	O	O	O	

F. Follow-up: 30 day (23 to 75 days post procedure); 1 year (305 to 425 days post procedure)

Follow-up Assessment Date[11000]: mm / dd / yyyy

Reference Episode Arrival Date/Time[11002]: mm / dd / yyyy HH:MM

Reference Episode Discharge Date[14338]: mm / dd / yyyy

Reference Procedure Start Date/Time[11001]: mm / dd / yyyy HH:MM

Reference Procedure Type[13705]: O TAVR O TMVr O TMVR O Tricuspid Valve Procedure

Method(s) to Determine Status[11003]:
☐ Office Visit ☐ Medical Records ☐ Letter from Medical Provider
☐ Phone Call ☐ Social Security Death Master File ☐ Hospitalized
☐ Obituary List ☐ CMS Linked Data ☐ Other

Follow-up Status[11004]: O Alive O Deceased O Lost to Follow-up

→ **If** Alive, **Residence**[13805]: O Home with No Health Aid O Home with Health Aid O Long Term Care O Other ☐ Not Documented[14511]

→ **If** Deceased, **Date of Death**[11006]: mm / dd / yyyy

→ **If** Deceased, **Cause of Death**[11007]:

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

Follow-Up Clinical Assessment

Hemoglobin[13775]: _____ g/dL ☐ Not Drawn[14326] **Creatinine**[13310]: _____ mg/dL ☐ Not Drawn[13311]

NYHA Classification[13688]: O I O II O III O IV ☐ Not Documented[14333]

12-Lead ECG Performed[13689]: O No O Yes

→**If** Yes, **12-Lead ECG Findings**[13621] *(Check all that apply)*: ☐ No Significant Changes ☐ Pathological Q Wave ☐ New LBBB ☐ Cardiac Arrhythmia

Follow-Up Imaging – Echocardiogram

Echocardiogram[13492]: O Yes - TTE O Yes - TEE ☐ Not Performed[14512] →**If** Yes, **Date**[13593]: mm / dd / yyyy

→**If** Yes, **LVEF**[13690]: _____ % ☐ LVEF Not Assessed[13691]

→**If** Yes, **Mitral Regurgitation**[13673]: O None O Trace/Trivial O Mild O Moderate O Moderate-Severe O Severe

→**If** Yes, **MV Mean Gradient**[13778]: (highest) _____ mm Hg

→**If** Yes, **Effective Regurgitant Orifice Area (EROA)**[13768]: _____ cm^2 →**If** EROA, **Method of Assessment**[13780]: O 3D Planimetry O PISA O Quantitative Dopplar O Other

→**If** Yes, **Left Ventricular Internal Systolic Dimension**[13783]: _____ cm ☐ Not Measured[14536]

→**If** Yes, **Left Ventricular Internal Diastolic Dimension**[13784]: _____ cm ☐ Not Measured[14537]

→**If** Yes, **Left Ventricular End Systolic Volume**[13786]: _____ mL ☐ Not Measured[14539]

→**If** Yes, **Left Ventricular End Diastolic Volume**[13785]: _____ mL ☐ Not Measured[14538]

→**If** Yes, **Left Atrial Volume**[13787]: _____ mL ☐ Not Measured[14540] (OR) **LA Volume Index**[13788]: _____ mL/m^2 ☐ Not Measured[14582]

Follow-Up Six Minute Walk Test and KCCQ

Six Minute Walk Test[13789]: O No O Yes

→**If** Yes, **Test Date**[13790]: mm / dd / yyyy →**If** Yes, **Total Distance**[14325]: _____ ft

→**If** No, **Reason**[14263]: O Non-Cardiac Reason O Cardiac Reason O Patient Not Willing to Walk O Not Performed by Site

KCCQ-12 Performed[13845]: O No O Yes →**If** Yes, **KCCQ-12 Date**[13844]: mm / dd / yyyy

→**If** Yes, **KCCQ-12**[13847, 69, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68]: (see separate questionnaire)

Q1a: _____ **Q1b:** _____ **Q1c:** _____ **Q2:** _____ **Q3:** _____ **Q4:** _____

Q5: _____ **Q6:** _____ **Q7:** _____ **Q8a:** _____ **Q8b:** _____ **Q8c:** _____

KCCQ Summary Score[14535]: (calculated) _____

Follow-up Medications

Category	Medication Code[11990]	Prescribed[13696]				→ If Yes, Loop Diuretic Dose[14577]
		Yes	No– No Reason	No– Medical Reason	No– Pt Reason	
ACE Inhibitors (Angiotensin Converting Enzyme)	Angiotensin Converting Enzyme Inhibitor	O	O	O	O	
Aldosterone Antagonist	Aldosterone Antagonist	O	O	O	O	
Anticoagulant	Direct Thrombin Inhibitor	O	O	O	O	
	Warfarin	O	O	O	O	
Antiplatelet	Aspirin	O	O	O	O	
ARB (Angiotensin Receptors Blockers)	Angiotensin II Receptor Blocker	O	O	O	O	
Beta Blockers	Beta Blocker	O	O	O	O	
Diuretics	Diuretics Not Otherwise Specified	O	O	O	O	
	Loop Diuretics	O	O	O	O	_____ mg
	Thiazides	O	O	O	O	
Non-Vitamin K Dependent Oral Anticoagulant	Direct Factor Xa Inhibitor	O	O	O	O	
P2Y12 Inhibitor	P2Y12 Antagonist	O	O	O	O	

Follow-up Events

Specify the events (and event dates) that occurred between discharge and 30 day (first) follow-up (FU), or between FU assessment date #1 and #2.

Event(s)[12933]	Event(s) Occurred[14276]	→ If Yes, Event Date(s)[14277]
ASD Defect Closure due to Transseptal Catheterization	O No O Yes	mm / dd / yyyy
Atrial Fibrillation	O No O Yes	mm / dd / yyyy
Bleeding – Life Threatening	O No O Yes	mm / dd / yyyy
Bleeding – Major	O No O Yes	mm / dd / yyyy
Cardiac Surgery or Intervention – Other Unplanned	O No O Yes	mm / dd / yyyy
COVID19	O No O Yes	mm / dd / yyyy
Device Embolization	O No O Yes	mm / dd / yyyy
Device Thrombosis	O No O Yes	mm / dd / yyyy
Device Related Event – Other	O No O Yes	mm / dd / yyyy
Dialysis (New Requirement)	O No O Yes	mm / dd / yyyy
Endocarditis	O No O Yes	mm / dd / yyyy
Myocardial Infarction	O No O Yes	mm / dd / yyyy
Permanent Pacemaker	O No O Yes	mm / dd / yyyy
Readmission – Cardiac (Not Heart Failure)	O No O Yes	mm / dd / yyyy
Readmission – Heart Failure (Complete event info)	O No O Yes	mm / dd / yyyy
Readmission – Non-Cardiac	O No O Yes	mm / dd / yyyy
Reintervention – Mitral Valve (Complete event info)	O No O Yes	mm / dd / yyyy
Single Leaflet Device Attachment	O No O Yes	mm / dd / yyyy
Stroke – Ischemic (complete event info)	O No O Yes	mm / dd / yyyy
Stroke – Hemorrhagic (complete event info)	O No O Yes	mm / dd / yyyy
Stroke – Undetermined (complete event info)	O No O Yes	mm / dd / yyyy
Transient Ischemic Attack (TIA) (complete event info)	O No O Yes	mm / dd / yyyy
Vascular Complication – Major	O No O Yes	mm / dd / yyyy
Vascular Complication – Minor	O No O Yes	mm / dd / yyyy
Vascular Surgery or Intervention – Unplanned	O No O Yes	mm / dd / yyyy

FOLLOW-UP EVENT INFORMATION (COMPLETE FOR EACH ISCHEMIC, HEMORRHAGIC, UNDETERMINED STROKE, TIA, MV RE-INTERVENTION OR HF READMISSION)

Event[14385]: **Event Date**[14386]: mm / dd / yyyy

O Ischemic Stroke (follow-up) O Hemorrhagic Stroke (follow-up) O Undetermened Stroke (follow-up) O TIA (follow-up)
O Mitral Valve Re-intervention (follow-up) O Heart Failure Readmission (follow-up)

Status[14387]: O Alive O Deceased →**If** Deceased, **Date of Death:**[14388]: mm / dd / yyyy

Clinical Comments[14463]:

→IF EVENT[14385] = STROKE OR TIA (FOLLOW-UP)

Symptom Onset Date[14389]: mm / dd / yyyy

Neurologic Deficit with Rapid Onset[14390]: O No O Yes

→**If** Yes, **Clinical Presentation**[14391]: O Stroke/TIA O Non-Stroke

→**If** Stroke/TIA, **Symptom Duration ≥ 24 hours**[14392]: O No O Yes

→**If** Stroke/TIA, **Brain Imaging Performed**[14393]: O No O Yes

→**If** Yes, **Brain Imaging Type**[14394]: O CT O CT w/Contrast O MRI O MRI w/Contrast O Other (e.g. angiography)

→**If** Yes, **Brain Imaging Findings**[14395]: O Infarct O Hemorrhage O No Deficit

→**If** Stroke/TIA, **Event Related Sequelae**[14396] *(Select all that apply)*: ☐ Death ☐ Permanent Vegetative State ☐ Altered Consciousness ☐ Blindness ☐ Aphasia ☐ Loss of Motor Function ☐ Loss of Sensory Function ☐ Facial Paralysis ☐ Prolonged Length of Stay ☐ Other

→**If** Status=Alive, **Discharge Location**[14420]: O Home O Skilled Nursing Facility O Extended Care/TCU/Rehab O Other Discharge Location

→**If** Status=Alive, **Patient Discharged to Prior Place of Living**[14422]: O No O Yes

→**If** Status=Deceased, **Stroke Diagnosed During Autopsy**[14397]: O No O Yes O Info Not Available

→IF EVENT[14385] = MITRAL VALVE RE-INTERVENTION (FOLLOW-UP)

Mitral Valve Re-intervention Type[14405]: O Surgical Replacement O Surgical Repair O Transcatheter Replacement O Balloon Valvuloplasty O Leaflet Clip Procedure O Paravalvular Leak Closure O Other Transcatheter Intervention

MV Re-intervention Indication[14406]: O Regurgitation O Stenosis O Device Embolization O Endocarditis O Device Thrombosis O Valve Injury O Other

→IF EVENT[14385] = READMISSION (HEART FAILURE)

Hospitalization >=24 Hours[14380]: O No O Yes O Information Not Available

Clinical Signs and/or Symptoms of Heart Failure[14381]: O No O Yes O Information Not Available

IV or Invasive Treatment Required[14382]: O No O Yes O Information Not Available

Note: IV includes diuretics or vasoactive therapy; invasive treatment includes ultrafiltration, IABP or mechanical assistance.