STS/ACC TVT Registry™

TVT Registry™ v1.1 – Data Collection Form
For Transcatheter Valve Replacement Procedures

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

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

Endocarditis[4000]: O No O Yes
→**If** Yes, **Infectious Endocarditis**[4005]: O Treated O Active
Permanent Pacemaker[4010]: O No O Yes
Previous ICD[4015]: O No O Yes
Prior PCI[4020]: O No O Yes
→**If** Yes, **Most Recent PCI Date**[4025]: mm / dd / yyyy
Prior CABG[4030]: O No O Yes
→**If** Yes, **Most Recent CABG Date**[4035]: mm / dd / yyyy
Prior Other Cardiac Surgery[4040]: 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, **Most Recent AV Procedure Date**[4065]: mm / dd / yyyy
→**If** Yes, **AV Replacement – Surgical**[4070]: O No O Yes
→**If** Yes, **AV Type**[4075]: O Bioprosthetic stented O Bioprosthetic stentless
→**If** Yes, **AV Repair – Surgical**[4080]: O No O Yes
→**If** Yes, **AV Balloon Valvuloplasty**[4085]: O No O Yes
→**If** Yes, **AV Transcatheter Valve Replacement**[4090]: O No O Yes
→**If** Yes, **AV Transcatheter Valve Intervention**[4091]: O No O Yes
Prior Non-Aortic Valve Procedure[4095]: O No O Yes
→**If** Yes, **MV Replacement – Surgical**[4100]: O No O Yes
→**If** Yes, **MV Type**[4105]: O Mechanical O Bioprosthetic
→**If** Yes, **MV Repair – Surgical**[4110]: 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** Right, Left or Both, **Prior CEA/CAS**[4140]: O No O Yes
→**If** Right, Both, **Right Carotid Severity**[4141]: O 80-99% O 100%
→**If** Left, Both, **Left Carotid Severity**[4142]: O 80-99% O 100%
→**If** Right, Left, Both, **Sx w/in 60 days**[4144]: O No O Yes
Peripheral Arterial Disease[4145]: O No O Yes
Current/Recent Smoker[4150]: (<1 Year) O No O Yes

Hypertension[4155]: O No O Yes
Dyslipidemia[4160]: 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

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

D. Pre-Procedure Status cont'd (complete for the procedure)

Heart Failure w/in 2 Weeks[5020]:	O No	O Yes	**Conduction Defect**[5055]:	O No O Yes
NYHA Class w/in 2 Weeks[5025]:	O I O II O III O IV		**Five Meter Walk Test**[5085]:	O No O Yes
Cardiogenic Shock w/in 24 Hours[5030]:	O No	O Yes	→**If** Yes**, Time 1**[5090]:	_____ seconds
Cardiac Arrest w/in 24 Hours[5035]:	O No	O Yes	→**If** Yes**, Time 2**[5095]:	_____ seconds
Cardiac Procedure w/in 30 Days[5040]:	O No	O Yes	→**If** Yes**, Time 3**[5100]:	_____ seconds
Porcelain Aorta[5045]:	O No	O Yes	**EuroSCORE II**[5110]:	_____ %
Atrial Fibrillation/Flutter[5050]:	O No	O Yes		

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]
Platelet Count[5260]:	_____ µL	☐ Not Drawn[5261]	**INR**[5265]:	_____	☐ Not Drawn[5266]
Albumin[5270]:	_____ g/dL	☐ Not Drawn[5271]	**Bilirubin**[5275]:	_____ mg/dL	☐ Not Drawn[5276]
FEV1 Predicted[5280]:	_____ %	☐ Not Performed[5281]	**DLCO Predicted**[5285]:	_____ %	☐ Not Performed[5286]

Medications (administered within 24 hours prior to the procedure)

Unfractionated Heparin[5400,5405]:	O No	O Yes	O Contraindicated	O Blinded
Anticoagulants[5400,5405]: (other)	O No	O Yes	O Contraindicated	O Blinded
Aspirin[5400,5405]:	O No	O Yes	O Contraindicated	O Blinded
Direct Thrombin Inhibitors[5400,5405]:	O No	O Yes	O Contraindicated	O Blinded
Inotropes[5400,5405]: (positive)	O No	O Yes	O Contraindicated	O Blinded

Diagnostic Cath Findings / Echocardiogram Findings

Diagnostic Cath[5500]: O No O Yes → **If** Yes**, Diagnostic Cath Date**[5505]: mm / dd / yyyy

Number of Diseased Vessels[5506]:	O None	O 1 O 2 O 3		
Left Main Stenosis >=50%[5507]:	O No	O Yes	**Left Atrial Area**[5592]:	_____ cm^2
Proximal LAD >=70%[5508]:	O No	O Yes	**Left Ventricular Internal Systolic Dimension**[5595]:	_____ cm
LVEF[5565]: _____ % ☐ LVEF Not Assessed[5566]			**Left Ventricular Internal Diastolic Dimension**[5600]:	_____ cm
Right Ventricular Systolic Pressure[5568]: (highest)	_____ mmHg		**Septal Wall Thickness**[5605]:	_____ cm
Pulmonary Capillary Wedge Pressure[5590]:	_____ mmHg		**Posterior Wall Thickness**[5610]:	_____ cm

AV Disease Etiology[5620]: O Degenerative O Endocarditis O Congenital O Rheumatic O Primary aortic disease O LV outflow tract obstruction O Supravalvular aortic stenosis O Tumor O Trauma O Other

Aortic Insufficiency[5630]: (highest) O None O Trace/Trivial O Mild O Moderate O Severe

Valve Morphology[5640]: O Unicuspid O Bicuspid O Tricuspid O Quadracuspid O Uncertain

Annular Calcification[5645]: O No O Yes

AV Peak Velocity (CW)[5650]: _____ m/s

AV Annulus Size[5655]: _____ mm

→**Annulus Size Assessment Method**[5660]: O TTE O TEE O CTA O Angiography

DIAGNOSTIC CATH FINDINGS / ECHOCARDIOGRAM FINDINGS CONT'D

Aortic Stenosis[5665]: O No O Yes

→**If** Yes, **AV Area**[5670]: (smallest) _____ cm^2

→**If** Yes, **AV Mean Gradient**[5675]: (highest) _____ mmHg

→**If** Yes, **AV Peak Gradient**[5680]: (highest) _____ mmHg

Mitral Valve Disease[5685]: O No O Yes

→**If** Yes, **Mitral Insufficiency**[5695]: (highest) O None O Trace/Trivial O Mild O Moderate O Severe

→**If** Yes, **Mitral Stenosis**[5705]: O No O Yes

→**If** Yes, **MV Area**[5710]: (smallest) _____ cm^2

→**If** Yes, **MV Mean Gradient**[5715]: (highest) _____ mmHg

Tricuspid Valve Disease[5720]: O No O Yes

→**If** Yes, **Tricuspid Insufficiency**[5735]: (highest) O None O Trace/Trivial O Mild O Moderate O Severe

E. PROCEDURE INFORMATION

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 Location[6050]: O Hybrid OR Suite O Hybrid Cath Suite O CathLab O Other

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

Primary Procedure Indication[6060]: O Primary AS O Primary AI O Mixed AS/AI O Failed Bioprosthetic Valve

Valve-in-Valve Procedure[6065]: O No O Yes →**If** Yes, **Status**[6070]: O Elective O Immediate intraprocedure

Operator Reason for Procedure[6071]:
O Patient preference
O Inoperable (technical)
O Prohibitive risk (co-morbid conditions)
O Prohibitive risk (debilitated/deconditioned patient)
O Other

Evaluation of Suitability for Open AVR by Two Surgeons[6072]: O No O Yes

Procedure Aborted[6075]: O No O Yes

→**If** Yes, **Reason**[6080]:
O Difficult arterial access
O Annulus too large for implant
O Transapical access issue
O Transaortic access issue
O Inability to navigate from access to valve
O Other

Conversion to Open Heart Surgery[6085]: O No O Yes

→**If** Yes, **Reason**[6090]:
O Valve dislodged to aorta
O Valve dislodged to left ventricle
O Ventricular rupture
O Annulus rupture
O Aortic dissection
O Coronary occlusion
O Other

Mechanical Assist Device in Place at Start of Procedure[6095]: O No O Yes – IABP O Yes - Catheter-based assist device (Impella, Tandem Heart)

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 Moderate sedation O General anesthesia O Epidural O Combination

Rapid Ventricular Pacing[6115]: O No O Yes →**If** Yes, **Total Pacing Time**[6116]: _____ mins

INTRA-PROCEDURE MEDICATIONS (ADMINISTERED DURING THE PROCEDURE)

Unfractionated Heparin[6120,6125]:	O No	O Yes	O Contraindicated	O Blinded
Anticoagulants[6120,6125]: (other)	O No	O Yes	O Contraindicated	O Blinded
Direct Thrombin Inhibitors[6120,6125]:	O No	O Yes	O Contraindicated	O Blinded
Inotropes[6120,6125]: (positive)	O No	O Yes	O Contraindicated	O Blinded

DEVICE INFORMATION

Minimum Lumen Diameter in Access Ilio-femoral Artery[6195]: _____ mm ☐ Not Accessed[6196]

Valve Sheath Access Site[6200]: O Femoral O Axillary O Transapical O Transaortic O Subclavian O Other

Valve Sheath Access Method[6205]: O Percutaneous O Cutdown O Mini thoracotomy O Mini sternotomy O Other

Valve Sheath Delivery Size[6210]: _____ French | **Largest Valvuloplasty Balloon Size**[6215]: (pre-implant) _____ mm

Device 1 Used[6225]: _____ Refer to Device List _____ | **Device Serial Number**[6230]: _____

Device 2 Used[6225]: _____ Refer to Device List _____ | **Device Success**[6235]: O No O Yes

HEMODYNAMICS	PRE-IMPLANT	POST-IMPLANT
Pulse[6310,6365]:	_____ bpm	_____ bpm
Aortic Sys/Diastolic Pressure[6315,6320,6370,6375]:	_____ / _____mmHg	_____ / _____mmHg
Mean Aortic Pressure[6325,6380]:	_____ mmHg	_____ mmHg
AV Gradient[6385,6390]:		**Mean:** _____ mmHg **Peak:** _____ mmHg
Calculated Aortic Valve Area[6340,6395]:	_____ cm^2	_____ cm^2
Cardiac Output[6345,6400]:	_____ L/min	_____ L/min

Contrast Volume[6450]: _____ ml

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

→**Fluoroscopy Time**[6460]: _____ minutes

→**Cumulative Air Kerma**[6465]: _____ mGy

→**Dose Area Product**[6470]: _____ →**DAP Units**[6475]: O Gy-cm2 O cGy-cm2 O mGy-cm2 O µGy-M2

F. ADVERSE EVENTS, INTERVENTIONS AND SURGICAL PROCEDURES (SPECIFY THE 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]:

Myocardial Infarction[E001]:	mm / dd / yyyy	**Hematoma at Access Site**[E018]:	mm / dd / yyyy
Coronary Compression or Obstruction[E002]:	mm / dd / yyyy	**Retroperitoneal Bleeding**[E019]:	mm / dd / yyyy
Endocarditis[E003]:	mm / dd / yyyy	**GI Bleed**[E020]:	mm / dd / yyyy
Conduction/Native Pacer Disturbance[E004]:	mm / dd / yyyy	**GU Bleed**[E021]:	mm / dd / yyyy
Cardiac Arrest[E005]:	mm / dd / yyyy	**Other Bleed**[E022]:	mm / dd / yyyy
Atrial Fibrillation[E006]:	mm / dd / yyyy	**Device Migration**[E023]:	mm / dd / yyyy
Annular Dissection[E007]:	mm / dd / yyyy	**Device Embolization Left Ventricle**[E024]:	mm / dd / yyyy
Aortic Dissection[E008]:	mm / dd / yyyy	**Device Embolization Aorta**[E025]:	mm / dd / yyyy
Perforation with or w/o Tamponade[E009]:	mm / dd / yyyy	**Device Recapture or Retrieval**[E026]:	mm / dd / yyyy
Transient Ischemic Attack[E010]: (complete Adjudication)	mm / dd / yyyy	**Device Thrombosis**[E027]:	mm / dd / yyyy
Ischemic Stroke[E011]: (complete Adjudication)	mm / dd / yyyy	**Other Device Related Event**[E028]:	mm / dd / yyyy
Hemorrhagic Stroke[E012]: (complete Adjudication)	mm / dd / yyyy	**New Requirement for Dialysis**[E029]:	mm / dd / yyyy
Undetermined Stroke[E013]: (complete Adjudication)	mm / dd / yyyy	**Aortic Valve Re-intervention**[E030]: (complete Adjudication)	mm / dd / yyyy
Transapical Related Event[E014]:	mm / dd / yyyy	**Unplanned Other Cardiac Surgery or Intervention**[E031]: (not AVR or PCI)	mm / dd / yyyy
Transortic Related Event[E015]:	mm / dd / yyyy	**Unplanned Vascular Surgery or Intervention**[E032]: (for Bleeding or Access Site Complication)	mm / dd / yyyy
Vascular Access Site Complication Req Rx[E016]:	mm / dd / yyyy	**PCI**[E033]:	mm / dd / yyyy
Bleeding at Access Site[E017]:	mm / dd / yyyy		

G. Post-Procedure Labs and Tests

Troponin[8000]: O No O Yes – I O Yes – T

→**If** Yes, **Date/Time**[8005,8006]: mm / dd / yyyy HH:MM

→**If** Yes, **Value**[8010]: _____ (ng/mL)

→**URL**[8015]: _____

CK[8020]: O Not Drawn O Drawn and normal O Drawn and not normal

→**If** not normal, **CK-MB Date/Time**[8025,8026]: mm / dd / yyyy HH:MM

→**If** not normal, **CK-MB Value**[8030]: _____ ng/mL

→ **ULN**[8035]: _____

Lowest Hemoglobin[8040]: _____ g/dL ☐ Not Drawn[8041]

Highest Creatinine[8050]: _____ mg/dL ☐ Not Drawn[8051]

Discharge Hemoglobin[8045]: _____ g/dL ☐ Not Drawn[8046]

Discharge Creatinine[8055]: _____ mg/dL ☐ Not Drawn[8056]

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** TTE, TEE, **Date**[8070]: mm / dd / yyyy

→**If** TTE, TEE, **Mitral Insufficiency**[8075]: O None O Trace/Trivial O Mild O Moderate O Severe

→**If** TTE, TEE, **Aortic Stenosis**[8080]: O No O Yes

→**If** TTE, TEE, **AV Area**[8085]: (smallest) _____ cm^2

→**If** TTE, TEE, **Mean Gradient**[8090]: (highest) _____ mmHg

→**If** TTE, TEE, **Aortic Insufficiency Severity**[8095]: O None O Trace/Trivial O Mild O Moderate O Severe

→**If** Trace/Trivial, Mild, Moderate, or Severe **Perivalvular Severity**[8106]: O None O Mild O Moderate O Severe

→**If** Trace/Trivial, Mild, Moderate, or Severe **Central Severity**[8107]: O None O Mild O Moderate O Severe

H. Discharge (Complete for each episode of care)

RBC/Whole Blood Transfusion[9011]: O No O Yes

→**If** Yes, **# Units Transfused**[9012]: _____

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

ACE Inhibitor[9100,9105]: (any)	O No	O Yes	O Contraindicated	O Blinded
Warfarin[9100,9105]:	O No	O Yes	O Contraindicated	O Blinded
ARB[9100,9105]: (any)	O No	O Yes	O Contraindicated	O Blinded
Aspirin[9100,9105]: (any)	O No	O Yes	O Contraindicated	O Blinded
Beta Blocker[9100,9105]: (any)	O No	O Yes	O Contraindicated	O Blinded
Antiarrhythmics[9100,9105]: (any)	O No	O Yes	O Contraindicated	O Blinded
Dabigatran[9100,9105]:	O No	O Yes	O Contraindicated	O Blinded
P2Y12[9100,9105]: (any)	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 (Note: if the patient has not been discharged at 30 days, capture the 30 day F/U at the date of discharge.)

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

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]

Anginal Class at Follow-up[10095]: O No angina O I O II O III O IV

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

Five Meter Walk[10135]: O No O Yes →**If** Yes, **Time 1**[10140]: _____ seconds **Time 2**[10145]: _____ seconds **Time 3**[10150]: _____ seconds

12-Lead ECG Findings[10155]: O Not performed O No significant changes O New changes noted

→**If** New changes noted, **ECG Changes Noted**[10160]: O Pathological Q-wave or LBBB O Arrhythmia O Both

Echocardiogram[10206]: O Not Performed O Yes - TTE O Yes - TEE →**If** TTE, TEE, **Date**[10207]: mm / dd / yyyy

→**If** TTE, TEE, **LVEF**[10210]: _____ % ☐ LVEF Not Assessed[10211]

→**If** TTE, TEE, **Mean Gradient**[10215]: (highest) _____ mmHg

→**If** TTE, TEE, **Aortic Insufficiency Severity**[10220]: O None O Trace/Trivial O Mild O Moderate O Severe

→**If** Trace/Trivial, Mild, Moderate, or Severe **Perivalvular Severity**[10225]: O None O Mild O Moderate O Severe

→**If** Trace/Trivial, Mild, Moderate, or Severe **Central Severity**[10227]: O None 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:** _____

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

Myocardial Infarction[E001]:	mm / dd / yyyy	**Unplanned Other Cardiac Surgery or Intervention**[E031]: (not AVR or PCI)	mm / dd / yyyy
Transient Ischemic Attack[E010]: (complete Adjudication)	mm / dd / yyyy	**Unplanned Vascular Surgery or Intervention**[E032]: (for Bleeding or Access Site Complication)	mm / dd / yyyy
Ischemic Stroke[E011]: (complete Adjudication)	mm / dd / yyyy	**PCI**[E033]:	mm / dd / yyyy
Hemorrhagic Stroke[E012]: (complete Adjudication)	mm / dd / yyyy	**Valve Related Readmission**[E034]:	mm / dd / yyyy
Undetermined Stroke[E013]: (complete Adjudication)	mm / dd / yyyy	**Non-Valve Related Readmission**[E035]:	mm / dd / yyyy
Transapical Related Event[E014]:	mm / dd / yyyy	**Major Vascular Complication**[E036]:	mm / dd / yyyy
New Requirement for Dialysis[E029]:	mm / dd / yyyy	**Life Threatening Bleeding**[E037]:	mm / dd / yyyy
Aortic Valve Re-intervention[E030]: (complete Adjudication)	mm / dd / yyyy	**Device Fracture**[E038]:	mm / dd / yyyy

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

ACE Inhibitor[10250,10255]:	O No	O Yes	O Contraindicated	O Blinded	**Aspirin**[10250,10255]:	O No	O Yes	O Contraindicated	O Blinded
Warfarin[10250,10255]:	O No	O Yes	O Contraindicated	O Blinded	**Beta Blocker**[10250,10255]:	O No	O Yes	O Contraindicated	O Blinded
ARB[10250,10255]:	O No	O Yes	O Contraindicated	O Blinded	**Antiarrhythmics**[10250,10255]:	O No	O Yes	O Contraindicated	O Blinded
Dabigatran[10250,10255]:	O No	O Yes	O Contraindicated	O Blinded	**P2Y12**[10250,10255]: (any)	O No	O Yes	O Contraindicated	O Blinded

J. Adjudication Form (Complete for EACH Ischemic, Hemorrhagic, Undetermined Stroke, TIA or Aortic Valve Re-intervention)

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 Stroke O TIA O Aortic Valve Re-intervention

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

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

→**If** Event[12000] = 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, **Therapeutic Intervention Performed**[12035]**:** 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

→**If** Stroke/TIA, **Lumbar Puncture Confirmation of Intracranial Hemorrhage**[12050]**:** O No O Yes

→**If** Stroke/TIA, **Neurologist/Neurosurgeon Confirmation of Diagnosis**[12055]**:** 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] = Aortic Valve Re-intervention

Aortic Valve Re-intervention Date[12100]**:** mm / dd / yyyy

Aortic Valve Re-intervention Type[12105]**:** O Surgical AV Repair/Replacement O Transcatheter AVR O Balloon Valvuloplasty O Other Transcatheter Intervention

→**If** Other Transcatheter Intervention, **Type**[12110]**:** _____

Primary Indication[12115]**:** O Aortic insufficiency O Aortic stenosis O Device migration O Device fracture O Endocarditis O Valve thrombosis O Other

→**If** Aortic Insufficiency**, AI Severity**[12120]**:** (highest) O None O Trace/Trivial O Mild O Moderate O Severe

→**If** Trace/Trivial, Mild, Moderate, or Severe **Perivalvular Severity**[12125]**:** O None O Mild O Moderate O Severe

→**If** Trace/Trivial, Mild, Moderate, or Severe **Central Severity**[12130]**:** O None O Mild O Moderate O Severe

→**If** Aortic Stenosis**, AS Severity**[12135]**:** (highest) O Possible stenosis O Significant stenosis

→**If** Other**, Other Indication**[12140]**:** _____

Clinical Comments[12145]**:** (information and details that may assist in assessing this re-intervention)