TAVR 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

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

Permanent Pacemaker[4010]: O No O Yes
→**If** Yes, **Previous Pacer Date**[4012]: mm / dd / yyyy

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 O Not Documented
→**If** Yes, **AV Model ID**[4078]: Refer to Device List
→**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 Transcath Valve Model ID**[4092]: Refer to Device List
→**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 stented O Bioprosthetic stentless O Not Documented
→**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 N/A

→**If** Right, Left or Both, **Prior CEA/CAS**[4140]: O No O Yes
→**If** R or B, **Rt Carotid Severity**[4141](%): O 50-79 O 80-99 O 100 O N/A
→**If** L or B, **Lt Carotid Severity**[4142](%): O 50-79 O 80-99 O 100 O N/A

Peripheral Arterial Disease[4145]: O No O Yes

Current/Recent Smoker[4150]: (<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

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

Heart Failure w/in 2 Weeks[5020]: O No O Yes

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

Cardiac Arrest w/in 24 Hours[5035]: O No O Yes

Cardiac Procedure w/in 30 Days[5040]: O No O Yes

Porcelain Aorta[5045]: O No O Yes

Conduction Defect[5055]: O No O Yes

Five Meter Walk Test[5085]: O Not performed O Yes O Unable to walk

→**If** Yes, **Time 1**[5090]: _____ seconds

→**If** Yes, **Time 2**[5095]: _____ seconds

→**If** Yes, **Time 3**[5100]: _____ seconds

STS Risk Score[5105]: _____ %:

Atrial Fibrillation/Flutter[5050]: O No O Yes

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

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 (Adjusted)[5285]: _____ % □ Not Performed[5286]

Medications (administered within 24 hours prior to the procedure)

Anticoagulants[5400,5405](any): 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

Proximal LAD >=70%[5508]: O No O Yes

Right Ventricular Systolic Pressure[5568]: (highest) _____ mmHg

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

Left Vent Internal Systolic Dim[5595]: _____ cm □ Not Measured[5608]

Left Vent Internal Diastolic Dim[5600]: _____ cm □ Not Measured[5609]

Septal Wall Thickness[5605]: _____ cm

Posterior Wall Thickness[5610]: _____ cm

Left Atrial Volume[5606]: ____ml **or** **LA Volume Index**[5607]:____ mL/m2

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 1+/Mild O 2+/Moderate O 3-4+/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.)

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 1+/mild O 2+/moderate O 3+/mod/severe O 4+/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 Insufficiency[5735]: (highest) O None O Trace/Trivial O Mild O Moderate O Severe

E. PROCEDURE INFORMATION

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 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 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)

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 Access related O Navigation Issue after successful access O Device/delivery system malfunction
O New clinical findings O Patient status O Consent Issue
O System issue O Other (not specified)

→**If** Yes, **Action**[6082]:
O Balloon valvuloplasty O Rescheduled transcatheter procedure O Conversion to open heart surgery
O Converted to medical therapy O Converted to clinical trial 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

INTRA-PROCEDURE MEDICATIONS (ADMINISTERED DURING THE PROCEDURE)

Inotropes[6120,6125]: (positive) O No O Yes O Contraindicated O Blinded

Device Information

Valve Sheath Access Site[6200]: O Femoral O Axillary O Transapical O Transaortic O Subclavian O Transiliac O Transseptal O Transcarotid 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

Device 1 Used[6225]: _____ Refer to Device List

Device 2 Used[6225]: _____ Refer to Device List

Device Serial Number[6230]:

UDI[6236, 6237, 6238]: _____ (future)

Device Implanted Successfully[6232]: O No O Yes

Device Success[6235]: O No O Yes

E. Procedure Information – Continued: Post Implant

AV Gradient (mean)[6385]: _____ mmHg

Calculated Aortic Valve Area[6395]: _____ cm^2

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[E059]:	mm / dd / yyyy	**Bleeding at Access Site**[E017]:	mm / dd / yyyy
Coronary Compression or Obstruction[E002]:	mm / dd / yyyy	**Hematoma at Access Site**[E018]:	mm / dd / yyyy
Endocarditis[E003]:	mm / dd / yyyy	**Retroperitoneal Bleeding**[E019]:	mm / dd / yyyy
Conduction/Native Pacer Disturbance Req Pacer[E039]:	mm / dd / yyyy	**GI Bleed**[E020]:	mm / dd / yyyy
Conduction/Native Pacer Disturbance Req ICD[E040]:	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
Transaortic Related Event[E015]:	mm / dd / yyyy	**Unplanned Vascular Surgery or Intervention**[E032]: (for Bleeding or Access Site Complication)	mm / dd / yyyy
Major Vascular Complication[E041]:	mm / dd / yyyy		
Minor Vascular Complication[E042]:	mm / dd / yyyy	**PCI**[E033]:	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]

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 Regurgitation**[8075]**:** O None O Trace/Trivial O 1+/mild O 2+/moderate O 3+/mod/severe O 4+/severe

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

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

→**If** TTE, TEE**, AV Peak Doppler Velocity**[8086]: _____ m/sec

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

→**If** TTE, TEE**, Aortic Insufficiency Severity**[8095]**:** O None O Trace/Trivial O 1+/Mild O 2+/Moderate O 3-4+/Severe

→**If** Trace/Trivial, Mild, Moderate, or Severe **Perivalvular Severity**[8106]**:** O None O Mild O Moderate O Severe O Not documented

→**If** Trace/Trivial, Mild, Moderate, or Severe **Central Severity**[8107]**:** O None O Mild O Moderate O Severe O Not documented

H. Discharge (Complete for each episode of care)

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

Note: Code the total # of units between start of the procedure and discharge

→**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
Dabigatran[9100,9105]**:**	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
P2Y12[9100,9105]**:** (any)	O No	O Yes	O Contraindicated	O Blinded
Factor Xa inhibitor[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 (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

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

Five Meter Walk[10135]**:** O Not performed O Yes O Unable to walk →**If** Yes**, Time 1**[10140]**:** ___ sec **Time 2**[10145]**:** ___ sec **Time 3**[10150]**:** ___ sec

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 1+/Mild O 2+/Moderate O 3-4+/Severe

→**If** Trace/Trivial, Mild, Moderate, or Severe **Perivalvular Severity**[10225]**:** O None O Mild O Moderate O Severe O Not documented

→**If** Trace/Trivial, Mild, Moderate, or Severe **Central Severity**[10227]**:** O None O Mild O Moderate O Severe O Not documented

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

→**If Yes, KCCQ-12**[10231-10242]**:** (See separate questionnaire)

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

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

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

Myocardial Infarction[E059]**:** mm / dd / yyyy	**Aortic Valve Re-intervention**[E030]**:** (complete Adjudication) mm / dd / yyyy
Endocarditis[E003]**:** mm / dd / yyyy	**Unplanned Other Cardiac Surgery or Intervention**[E031]**:** (not AVR or PCI) mm / dd / yyyy
Conduction/Native Pacer Disturbance Req Pacer[E039]**:** mm / dd / yyyy	**Unplanned Vascular Surgery or Intervention**[E032]**:** mm / dd / yyyy (for Bleeding or Access Site Complication)
Conduction/Native Pacer Disturbance Req ICD[E040]**:** mm / dd / yyyy	**PCI**[E033]**:** mm / dd / yyyy
Transient Ischemic Attack[E010]**:** (complete Adjudication) mm / dd / yyyy	**Valve Related Readmission**[E034]**:** mm / dd / yyyy
Ischemic Stroke[E011]**:** (complete Adjudication) mm / dd / yyyy	**Non-Valve Related Readmission**[E035]**:** mm / dd / yyyy
Hemorrhagic Stroke[E012]**:** (complete Adjudication) mm / dd / yyyy	**Major Vascular Complication**[E041]**:** mm / dd / yyyy
Undetermined Stroke[E013]**:** (complete Adjudication) mm / dd / yyyy	**Minor Vascular Complication**[E042]**:** mm / dd / yyyy
Device Fracture[E038]**:** mm / dd / yyyy	**Transapical Related Event**[E014]**:** mm / dd / yyyy
Device Thrombosis[E027]**:** mm / dd / yyyy	**Major Bleeding Event**[E043]**:** mm / dd / yyyy
New Requirement for Dialysis[E029]**:** mm / dd / yyyy	**Life Threatening Bleeding**[E037]**:** 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	**Beta Blocker**[10250,10255]**:** O No O Yes O Contraindicated O Blinded
Warfarin[10250,10255]**:** O No O Yes O Contraindicated O Blinded	**Antiarrhythmics**[10250,10255] O No O Yes O Contraindicated O Blinded
ARB[10250,10255]**:** O No O Yes O Contraindicated O Blinded	**P2Y12**[10250,10255]**:** (any) O No O Yes O Contraindicated O Blinded
Aspirin[10250,10255]**:** O No O Yes O Contraindicated O Blinded	**Factor Xa inhibitor**[10250,10255] O No O Yes O Contraindicated O Blinded
Dabigatran[10250,10255]**:** 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 Ischemic Stroke(In-hospital) O Hemorrhagic Stroke(In-hospital) O Undetermined Stroke(In-hospital) O TIA(In-hospital) O Aortic 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 Aortic Valve Re-intervention(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] = 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] = 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 1+/Mild O 2+/Moderate O 3-4+/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)