



TAVR Data Collection Form v2.1

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 : Male Female		Hispanic or Latino Ethnicity ²⁰⁷⁶ : No Yes	
Race: White ²⁰⁷⁰ (check all that apply) American Indian/Alaskan Native ²⁰⁷³		Black/African American ²⁰⁷¹ Native Hawaiian/Pacific Islander ²⁰⁷⁴		Asian ²⁰⁷²	

B. EPISODE OF CARE

Arrival Date/Time ^{3000,3001} : mm / dd / yyyy HH:MM					
Insurance Payors: Private Health Insurance ³⁰⁰⁵ (check all that apply) State-Specific Plan (non-Medicaid) ³⁰⁰⁹		Medicare ³⁰⁰⁶ Indian Health Service ³⁰¹⁰		Medicaid ³⁰⁰⁷ Non-US Insurance ³⁰¹¹	
Military Health Care ³⁰⁰⁸ None ³⁰¹²		HIC ³⁰¹⁵ : Research Study ³⁰³⁰ : No Yes <input checked="" type="checkbox"/> 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 : No Yes <input checked="" type="checkbox"/> If Yes, Infective Endocarditis Type ⁴⁰⁰⁵ : Treated Active		Prior Aortic Valve Procedure ⁴⁰⁶⁰ : No Yes <input checked="" type="checkbox"/> If Yes, Most Recent AV Procedure Date ⁴⁰⁶⁵ : mm / dd / yyyy	
Permanent Pacemaker ⁴⁰¹⁰ : No Yes <input checked="" type="checkbox"/> If Yes, Previous Pacer Date ⁴⁰¹² : mm / dd / yyyy		<input checked="" type="checkbox"/> If Yes, AV Replacement – Surgical ⁴⁰⁷⁰ : No Yes <input checked="" type="checkbox"/> If Yes, AV Type ⁴⁰⁷⁵ : Bioprosthetic stented Bioprosthetic stentless Not Documented	
Previous ICD ⁴⁰¹⁵ : No Yes		<input checked="" type="checkbox"/> If Yes, AV Model ID ⁴⁰⁷⁸ : <u>Refer to Device List</u>	
Prior PCI ⁴⁰²⁰ : No Yes <input checked="" type="checkbox"/> If Yes, Most Recent PCI Date ⁴⁰²⁵ : mm / dd / yyyy		<input checked="" type="checkbox"/> If Yes, AV Repair – Surgical ⁴⁰⁸⁰ : No Yes	
Prior CABG ⁴⁰³⁰ : No Yes <input checked="" type="checkbox"/> If Yes, Most Recent CABG Date ⁴⁰³⁵ : mm / dd / yyyy		<input checked="" type="checkbox"/> If Yes, AV Balloon Valvuloplasty ⁴⁰⁸⁵ : No Yes	
Prior Other Cardiac Surgery ⁴⁰⁴⁰ : No Yes		<input checked="" type="checkbox"/> If Yes, AV Transcatheter Valve Replacement ⁴⁰⁹⁰ : No Yes	
# Previous Cardiac Surgeries ⁴⁰⁵⁵ : 0 1 2 3 >=4		<input checked="" type="checkbox"/> If Yes, AV Transcath Valve Model ID ⁴⁰⁹² : <u>Refer to Device List</u>	
		<input checked="" type="checkbox"/> If Yes, AV Transcatheter Valve Intervention ⁴⁰⁹¹ : No Yes	
		Prior Non-Aortic Valve Procedure ⁴⁰⁹⁵ : No Yes	
		<input checked="" type="checkbox"/> If Yes, MV Replacement – Surgical ⁴¹⁰⁰ : No Yes	
		<input checked="" type="checkbox"/> If Yes, MV Type ⁴¹⁰⁵ : Mechanical Bioprosthetic stented Bioprosthetic stentless Not Documented	
		<input checked="" type="checkbox"/> If Yes, MV Repair – Surgical ⁴¹¹⁰ : No Yes	

OTHER HISTORY AND RISK FACTORS

Prior Stroke ⁴¹²⁰ : No Yes <input checked="" type="checkbox"/> If Yes, Most Recent Stroke Date ⁴¹²⁵ : mm / dd / yyyy		Hypertension ⁴¹⁵⁵ : No Yes	
Transient Ischemic Attack ⁴¹³⁰ : No Yes		Diabetes Mellitus ⁴¹⁶⁵ : No Yes	
Carotid Stenosis ⁴¹³⁵ : None Right Left Both N/A <input checked="" type="checkbox"/> If Right, Left or Both, Prior CEA/CAS ⁴¹⁴⁰ : No Yes <input checked="" type="checkbox"/> If R or B, Rt Carotid Severity ⁴¹⁴¹ (%): 50-79 80-99 100 N/A <input checked="" type="checkbox"/> If L or B, Lt Carotid Severity ⁴¹⁴² (%): 50-79 80-99 100 N/A		<input checked="" type="checkbox"/> If Yes, Diabetes Therapy ⁴¹⁷⁰ : None Diet Oral Insulin Other	
Peripheral Arterial Disease ⁴¹⁴⁵ : No Yes		Currently on Dialysis ⁴¹⁷⁵ : No Yes	
Current/Recent Smoker ⁴¹⁵⁰ : (<1 Year) No Yes		Chronic Lung Disease ⁴¹⁸⁰ : None Mild Moderate Severe	
		Home Oxygen ⁴¹⁸¹ : No Yes	
		Hostile Chest ⁴¹⁸² : No Yes	
		Immunocompromise Present ⁴¹⁸⁵ : No Yes	



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D. PRE-PROCEDURE STATUS (COMPLETE FOR THE PROCEDURE)

CAD Presentation ⁵⁰⁰⁰ : No Sxs, no angina (14 days) Unstable angina (60 days)	Sx unlikely to be ischemic (14 days) Non-STEMI (7 days)	Stable angina (42 days) STEMI (7 days)
Prior MI ⁵⁰⁰⁵ : No Yes	<input type="checkbox"/> If Yes, Prior MI Timeframe ⁵⁰¹⁰ : < 30 Days	>= 30 days
Heart Failure w/in 2 Weeks ⁵⁰²⁰ : No Yes	Conduction Defect ⁵⁰⁵⁵ : No Yes	
NYHA Class w/in 2 Weeks ⁵⁰²⁵ : I II III IV	Five Meter Walk Test ⁵⁰⁸⁵ : Not performed Yes Unable to walk	
Cardiogenic Shock w/in 24 Hours ⁵⁰³⁰ : No Yes	<input type="checkbox"/> If Yes, Time 1 ⁵⁰⁹⁰ : _____ seconds	
Cardiac Arrest w/in 24 Hours ⁵⁰³⁵ : No Yes	<input type="checkbox"/> If Yes, Time 2 ⁵⁰⁹⁵ : _____ seconds	
Cardiac Procedure w/in 30 Days ⁵⁰⁴⁰ : No Yes	<input type="checkbox"/> If Yes, Time 3 ⁵¹⁰⁰ : _____ seconds	
Porcelain Aorta ⁵⁰⁴⁵ : No Yes	STS Risk Score ⁵¹⁰⁵ : _____ %:	
Atrial Fibrillation/Flutter ⁵⁰⁵⁰ : No Yes	<input type="checkbox"/> If Yes, AF Class w/in past 30 days ⁵⁰⁵² : None Persistent Paroxysmal	
KCCQ-12 Performed ⁵¹⁶⁹ : No Yes	<input type="checkbox"/> 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 <input type="checkbox"/> Not Drawn ⁵²⁵¹	Creatinine ⁵²⁵⁵ : _____ mg/dL <input type="checkbox"/> Not Drawn ⁵²⁵⁶
Platelet Count ⁵²⁶⁰ : _____ μ L <input type="checkbox"/> Not Drawn ⁵²⁶¹	INR ⁵²⁶⁵ : _____ <input type="checkbox"/> Not Drawn ⁵²⁶⁶
Albumin ⁵²⁷⁰ : _____ g/dL <input type="checkbox"/> Not Drawn ⁵²⁷¹	Bilirubin ⁵²⁷⁵ : _____ mg/dL <input type="checkbox"/> Not Drawn ⁵²⁷⁶
FEV1 Predicted ⁵²⁸⁰ : _____ % <input type="checkbox"/> Not Performed ⁵²⁸¹	DLCO (Adjusted) ⁵²⁸⁵ : _____ % <input type="checkbox"/> Not Performed ⁵²⁸⁶

MEDICATIONS (ADMINISTERED WITHIN 24 HOURS PRIOR TO THE PROCEDURE)

Anticoagulants ^{5400,5405} (any): No Yes Contraindicated Blinded	Inotropes ^{5400,5405} (positive): No Yes Contraindicated Blinded
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DIAGNOSTIC CATH FINDINGS / ECHOCARDIOGRAM FINDINGS

Diagnostic Cath ⁵⁵⁰⁰ : No Yes	<input type="checkbox"/> If Yes, Diagnostic Cath Date ⁵⁵⁰⁵ : mm / dd / yyyy
Number of Diseased Vessels ⁵⁵⁰⁶ : None 1 2 3	Left Vent Internal Systolic Dim ⁵⁵⁹⁵ : _____ cm <input type="checkbox"/> Not Measured ⁵⁶⁰⁸
Left Main Stenosis >=50% ⁵⁵⁰⁷ : No Yes	Left Vent Internal Diastolic Dim ⁵⁶⁰⁰ : _____ cm <input type="checkbox"/> Not Measured ⁵⁶⁰⁹
Proximal LAD >=70% ⁵⁵⁰⁸ : No Yes	Septal Wall Thickness ⁵⁶⁰⁵ : _____ cm
Right Ventricular Systolic Pressure ⁵⁵⁶⁸ : (highest) _____ mmHg	Posterior Wall Thickness ⁵⁶¹⁰ : _____ cm
LVEF ⁵⁵⁶⁵ : _____ % <input type="checkbox"/> LVEF Not Assessed ⁵⁵⁶⁶	Left Atrial Volume ⁵⁶⁰⁶ : _____ ml or LA Volume Index ⁵⁶⁰⁷ : _____ mL/m ²
AV Disease Etiology ⁵⁶²⁰ : Degenerative Endocarditis Congenital Rheumatic Primary aortic disease LV outflow tract obstruction Supravalvular aortic stenosis Tumor Trauma Other	
Aortic Insufficiency ⁵⁶³⁰ : (highest) None Trace/Trivial 1+/Mild 2+/Moderate 3-4+/Severe	
Valve Morphology ⁵⁶⁴⁰ : Unicuspid Bicuspid Tricuspid Quadracuspid Uncertain	
Annular Calcification ⁵⁶⁴⁵ : No Yes	
AV Peak Velocity (CW) ⁵⁶⁵⁰ : _____ m/s	
AV Annulus Size ⁵⁶⁵⁵ : _____ mm	
<input type="checkbox"/> Annulus Size Assessment Method ⁵⁶⁶⁰ : TTE TEE CTA Angiography	



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DIAGNOSTIC CATH FINDINGS / ECHOCARDIOGRAM FINDINGS (CONT.)

Aortic Stenosis ⁵⁶⁶⁵ :	No	Yes				
<input type="checkbox"/> If Yes, AV Area ⁵⁶⁷⁰ : (smallest)	_____cm ²					
<input type="checkbox"/> If Yes, AV Mean Gradient ⁵⁶⁷⁵ : (highest)	_____mmHg					
<input type="checkbox"/> If Yes, AV Peak Gradient ⁵⁶⁸⁰ : (highest)	_____mmHg					
Mitral Valve Disease ⁵⁶⁸⁵ :	No	Yes				
<input type="checkbox"/> If Yes, Mitral Insufficiency ⁵⁶⁹⁵ : (highest)	None	Trace/Trivial	1+/mild	2+/moderate	3+/mod/severe	4+/severe
<input type="checkbox"/> If Yes, Mitral Stenosis ⁵⁷⁰⁵ :	No	Yes				
<input type="checkbox"/> If Yes, MV Area ⁵⁷¹⁰ : (smallest)	_____cm ²					
<input type="checkbox"/> If Yes, MV Mean Gradient ⁵⁷¹⁵ : (highest)	_____mmHg					
Tricuspid Insufficiency ⁵⁷³⁵ : (highest)	None	Trace/Trivial	Mild	Moderate	Severe	

E. PROCEDURE INFORMATION

Procedures:	<input type="checkbox"/> Transcatheter Aortic Valve Replacement ⁶⁶⁰⁰					<input type="checkbox"/> Transcatheter Mitral Valve Replacement ⁶⁶⁰¹					<input type="checkbox"/> Mitral Leaflet Clip Procedure ⁶⁶⁰²					
Other Procedure Performed Concurrently ⁶⁶²⁰ :	No	Yes-PCI	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 :	Hybrid OR Suite		Hybrid Cath Suite		CathLab		Other									
Procedure Status ⁶⁰⁵⁵ :	Elective		Urgent		Emergency		Salvage									
Primary Procedure Indication ⁶⁰⁶⁰ :	Primary AS		Primary AI		Mixed AS/AI		Failed Bioprosthetic Valve									
Valve-in-Valve Procedure ⁶⁰⁶⁵ :	No	Yes	<input type="checkbox"/> If Yes, Status ⁶⁰⁷⁰ :		Elective		Immediate intraprocedure									
Operator Reason for Procedure ⁶⁰⁷¹ :	Inoperable/Extreme Risk (technically inoperable, co-morbid or deconditioned patient) High risk (>=8% risk of 30 day mortality) Intermediate risk (4-7% risk of 30 day mortality) Low risk (<4% risk of 30 day mortality)															
Evaluation of Suitability for Open AVR by Two Surgeons ⁶⁰⁷² :	No	Yes														
Procedure Aborted ⁶⁰⁷⁵ :	No	Yes														
<input type="checkbox"/> If Yes, Reason ⁶⁰⁸⁰ :	Access related			Navigation Issue after successful access					Device/delivery system malfunction							
	New clinical findings			Patient status					Consent Issue							
	System issue			Other (not specified)												
<input type="checkbox"/> If Yes, Action ⁶⁰⁸² :	Balloon valvuloplasty			Rescheduled transcatheter procedure					Conversion to open heart surgery							
	Converted to medical therapy			Converted to clinical trial					Other							
Conversion to Open Heart Surgery ⁶⁰⁸⁵ :	No	Yes														
<input type="checkbox"/> If Yes, Reason ⁶⁰⁹⁰ :	Valve dislodged to aorta			Valve dislodged to left ventricle			Ventricular rupture			Other						
	Annulus rupture			Aortic dissection			Coronary occlusion									
Mechanical Assist Device in Place at Start of Procedure ⁶⁰⁹⁵ :	No	Yes - IABP		Yes - Catheter-based assist device (Impella, Tandem Heart)												
CardioPulmonary Bypass Used ⁶¹⁰⁰ :	No	Yes														
<input type="checkbox"/> If Yes, Status ⁶¹⁰¹ :	Elective		Emergent		<input type="checkbox"/> If Yes, CPB Time ⁶¹⁰⁵ : _____mins											
Type of Anesthesia ⁶¹¹⁰ :	Moderate sedation		General anesthesia		Epidural		Combination									

INTRA-PROCEDURE MEDICATIONS (ADMINISTERED DURING THE PROCEDURE)

Inotropes ^{6120,6125} : (positive)	No	Yes	Contraindicated	Blinded
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DEVICE INFORMATION

Valve Sheath Access Site ⁶²⁰⁰ : Femoral Transiliac	Axillary Transseptal	Transapical Transcarotid	Transaortic Transcaaval	Subclavian Other
Valve Sheath Access Method ⁶²⁰⁵ : Percutaneous	Cutdown	Mini thoracotomy	Mini sternotomy	Other
Valve Sheath Delivery Size ⁶²¹⁰ : _____ French	Device Serial Number ⁶²³⁰ : _____ UDI ^{6236, 6237, 6238} : _____ (future) _____			
Device 1 Used ⁶²²⁵ : Refer to Master Device List (code all valves, embolic protection, valve fracture and the BASILICA)	Device Implanted Successfully ⁶²³² : No			Yes
Device 2 Used ⁶²²⁵ : protection, valve fracture and the BASILICA)	Device Success ⁶²³⁵ : No			Yes

E. PROCEDURE INFORMATION – CONTINUED: POST IMPLANT

AV Gradient (mean)⁶³⁸⁵: _____ mmHg

Calculated Aortic Valve Area⁶³⁹⁵: _____ cm²

Contrast Volume⁶⁴⁵⁰: _____ ml

Radiation Dose Measurement Method⁶⁴⁵⁵: Single Plane Biplane

Fluoroscopy Time⁶⁴⁶⁰: _____ minutes

Cumulative Air Kerma⁶⁴⁶⁵: _____ mGy

Dose Area Product⁶⁴⁷⁰: _____ DAP Units⁶⁴⁷⁵: Gy-cm2 cGy-cm2 mGy-cm2 μGy-M2

F. ADVERSE EVENTS, INTERVENTIONS AND SURGICAL PROCEDURES (SPECIFY THE EVENT DATE FOR EACH EVENT OCCURRENCE.)

Intra or Post Procedure Events Occurred ⁷³⁰⁰ : No Yes	<input type="checkbox"/> 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} : / 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} : mm / dd / yyyy (not AVR or PCI)		
Transaortic Related Event ^{E015} : mm / dd / yyyy		Unplanned Vascular Surgery or Intervention ^{E032} : mm / dd / yyyy (for Bleeding or Access Site Complication)	
Major Vascular Complication ^{E041} : mm / dd / yyyy	PCI ^{E033} : mm / dd / yyyy		
Minor Vascular Complication ^{E042} : mm / dd / yyyy			



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G. POST-PROCEDURE LABS AND TESTS

Lowest Hemoglobin⁸⁰⁴⁰: _____ g/dL Not Drawn⁸⁰⁴¹ Highest Creatinine⁸⁰⁵⁰: _____ mg/dL Not Drawn⁸⁰⁵¹

Discharge Creatinine⁸⁰⁵⁵: _____ mg/dL Not Drawn⁸⁰⁵⁶

12-Lead ECG Findings⁸⁰⁶⁰: Not performed No significant changes New pathological Q-wave or LBBB

Echocardiogram⁸⁰⁶⁵: Not Performed Yes - TTE Yes - TEE

If TTE, TEE, Date⁸⁰⁷⁰: mm / dd / yyyy

If TTE, TEE, Mitral Regurgitation⁸⁰⁷⁵: None Trace/Trivial 1+/mild 2+/moderate 3+/mod/severe 4+/severe

If TTE, TEE, Aortic Stenosis⁸⁰⁸⁰: No Yes

If TTE, TEE, AV Area⁸⁰⁸⁵: (smallest) _____ cm²

If TTE, TEE, AV Peak Doppler Velocity⁸⁰⁸⁶: _____ m/sec

If TTE, TEE, Mean Gradient⁸⁰⁹⁰: (highest) _____ mmHg

If TTE, TEE, Aortic Insufficiency Severity⁸⁰⁹⁵: None Trace/Trivial 1+/Mild 2+/Moderate 3-4+/Severe

If Trace/Trivial, Mild, Moderate, or Severe Perivalvular Severity⁸¹⁰⁶: None Mild Moderate Severe Not documented

If Trace/Trivial, Mild, Moderate, or Severe Central Severity⁸¹⁰⁷: None Mild Moderate Severe Not documented

H. DISCHARGE (COMPLETE FOR EACH EPISODE OF CARE)

RBC/Whole Blood Transfusion⁹⁰¹¹: No Yes

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

If Yes, # Units Transfused⁹⁰¹²: _____

Number of Hours in ICU⁹⁰⁴⁰: _____

Discharge Date⁹⁰⁴⁵: mm / dd / yyyy

Discharge Status⁹⁰⁵⁰: Alive Deceased

If Alive, Discharge Location⁹⁰⁵⁵: Home Extended care/TCU/rehab Other acute care hospital
Nursing home Hospice Other Left against medical advice (AMA)

If Deceased, Death in Lab/OR⁹⁰⁶⁰: No Yes

If Deceased, Primary Cause of Death⁹⁰⁶⁵: Cardiac Neurologic Renal Vascular Infection
Valvular Pulmonary Unknown 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) No Yes Contraindicated Blinded

Warfarin^{9100,9105}: No Yes Contraindicated Blinded

ARB^{9100,9105}: (any) No Yes Contraindicated Blinded

Aspirin^{9100,9105}: (any) No Yes Contraindicated Blinded

Dabigatran^{9100,9105}: No Yes Contraindicated Blinded

Beta Blocker^{9100,9105}: (any) No Yes Contraindicated Blinded

Antiarrhythmics^{9100,9105}: (any) No Yes Contraindicated Blinded

P2Y12^{9100,9105}: (any) No Yes Contraindicated Blinded

Factor Xa inhibitor^{9100,9105}: (any) No Yes Contraindicated Blinded



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I. FOLLOW-UP (30 DAYS, 1 YEAR FROM DATE OF PROCEDURE)

Last Name²⁰⁰⁰: _____ First Name²⁰¹⁰: _____ Patient ID²⁰⁴⁰: _____
 Reference Procedure Start Date⁶⁰⁴⁰: mm / dd / yyyy Other ID²⁰⁴⁵: _____ Study Patient ID³⁰³²: (optional)

Assessment Date¹⁰⁰⁰⁰: 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 Status¹⁰⁰⁰⁵: Clinic Medical record Letter from medical provider
 Phone call to patient/family Social Security death master file Other

Status¹⁰⁰¹⁰: Alive Deceased Lost to follow-up Withdrawn
 If Deceased, Primary Cause of Death¹⁰⁰¹⁵: Cardiac Neurologic Renal Vascular Infection
 Valvular Pulmonary Unknown Other

If Deceased, Date of Death¹⁰⁰²⁰: mm / dd / yyyy

Hemoglobin¹⁰⁰⁸⁵: _____ g/dL Not Drawn¹⁰⁰⁸⁶ Creatinine¹⁰⁰⁹⁰: _____ mg/dL Not Drawn¹⁰⁰⁹¹

NYHA Classification at Follow-up¹⁰¹⁰⁰: I II III IV

Five Meter Walk¹⁰¹³⁵: Not performed Yes Unable to walk If Yes, Time 1¹⁰¹⁴⁰: _____ sec Time 2¹⁰¹⁴⁵: _____ sec Time 3¹⁰¹⁵⁰: _____ sec

12-Lead ECG Findings¹⁰¹⁵⁵: Not performed No significant changes New changes noted
 If New changes noted, ECG Changes Noted¹⁰¹⁶⁰: Pathological Q-wave or LBBB Arrhythmia Both

Echocardiogram¹⁰²⁰⁶: Not Performed Yes - TTE Yes - TEE If TTE, TEE, Date¹⁰²⁰⁷: mm / dd / yyyy
 If TTE, TEE, LVEF¹⁰²¹⁰: _____ % LVEF Not Assessed¹⁰²¹¹ If TTE, TEE, Mean Gradient¹⁰²¹⁵: (highest) _____ mmHg

If TTE, TEE, Aortic Insufficiency Severity¹⁰²²⁰: None Trace/Trivial 1+/Mild 2+/Moderate 3-4+/Severe
 If Trace/Trivial, Mild, Moderate, or Severe Perivalvular Severity¹⁰²²⁵: None Mild Moderate Severe Not documented
 If Trace/Trivial, Mild, Moderate, or Severe Central Severity¹⁰²²⁷: None Mild Moderate Severe Not documented

KCCQ-12 Performed¹⁰²³⁰: No Yes
 If Yes, KCCQ-12¹⁰²³¹⁻¹⁰²⁴²: Q1a: _____ Q1b: _____ Q1c: _____ Q2: _____ Q3: _____ Q4: _____
 (See separate questionnaire)
 Q5: _____ Q6: _____ Q7: _____ Q8a: _____ Q8b: _____ Q8c: _____



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STS/ACC
TVT Registry™

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) Occurred¹⁰²⁴⁵: No Yes If Yes, specify the Event¹⁰²⁴⁶ 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} : (for Bleeding or Access Site Complication)	mm / dd / yyyy
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} : No Yes Contraindicated Blinded	Beta Blocker ^{10250,10255} : No Yes Contraindicated Blinded
Warfarin ^{10250,10255} : No Yes Contraindicated Blinded	Antiarrhythmics ^{10250,10255} : No Yes Contraindicated Blinded
ARB ^{10250,10255} : No Yes Contraindicated Blinded	P2Y12 ^{10250,10255} : (any) No Yes Contraindicated Blinded
Aspirin ^{10250,10255} : No Yes Contraindicated Blinded	Factor Xa inhibitor ^{10250,10255} : No Yes Contraindicated Blinded
Dabigatran ^{10250,10255} : No Yes Contraindicated Blinded	

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TAVR Data Collection Form v2.1

J. ADJUDICATION FORM (COMPLETE FOR EACH ISCHEMIC, HEMORRHAGIC, UNDETERMINED STROKE, TIA OR AORTIC VALVE RE-INTERVENTION)

Last Name²⁰⁰⁰: _____ First Name²⁰¹⁰: _____ Patient ID²⁰⁴⁰: _____

Reference Procedure Start Date⁶⁰⁴⁰: mm / dd / yyyy Other ID²⁰⁴⁵: _____ Study Patient ID³⁰³²: (optional) _____

Adjudication Event¹²⁰⁰⁰:

Ischemic Stroke(In-hospital) Hemorrhagic Stroke(In-hospital) Undetermined Stroke(In-hospital) TIA(In-hospital) Aortic Valve Re-intervention(In-hospital) Ischemic Stroke(F-U) Hemorrhagic Stroke(F-U) Undetermined Stroke(F-U) TIA(F-U) Aortic Valve Re-intervention(F-U)

Event Date¹²⁰⁰⁵: mm / dd / yyyy

Status¹²⁰¹⁰: Alive Deceased If Deceased, Date of Death¹²⁰¹¹: mm / dd / yyyy

IF EVENT¹²⁰⁰⁰ = STROKE OR TIA

Date of Symptom Onset¹²⁰¹⁵: (approximate) mm / dd / yyyy

Neurologic Deficit with Rapid Onset¹²⁰²⁰: No Yes

If Yes, Clinical Presentation¹²⁰²⁵: Stroke/TIA Non-Stroke

If Stroke/TIA, Symptom Duration ≥ 24 hours¹²⁰³⁰: No Yes

If Stroke/TIA, Neuroimaging Performed¹²⁰⁴⁰: No Yes

If Yes, Deficit Type¹²⁰⁴⁵: No deficit Infarction Hemorrhage Both (hem/infarc) Subarachnoid Hemorrhage

If Stroke/TIA, Neurologist/Neurosurgeon Confirmation of Diagnosis¹²⁰⁵⁵: No Yes

If Stroke/TIA, Social/Recreational Activities Impaired¹²⁰⁵⁶: No Yes

If Stroke/TIA, Neurocognitive Functions Essential to Pt or their Livelihood Impaired¹²⁰⁵⁷: No Yes

If Stroke/TIA, New Aids or Assistance Required¹²⁰⁵⁸: No Yes

If Stroke/TIA, Death as a Result of Neurologic Deficit¹²⁰⁶⁰: No Yes

Clinical Comments¹²⁰⁶⁵: (information and details that may assist in assessing the stroke or TIA)

IF EVENT¹²⁰⁰⁰ = AORTIC VALVE RE-INTERVENTION

Aortic Valve Re-intervention Date¹²¹⁰⁰: mm / dd / yyyy

Aortic Valve Re-intervention Type¹²¹⁰⁵: Surgical AV Repair/Replacement Balloon Valvuloplasty Transcatheter AVR Other Transcatheter Intervention

If Other Transcatheter Intervention, Type¹²¹¹⁰: _____

Primary Indication¹²¹¹⁵: Aortic insufficiency Aortic stenosis Device migration Device fracture Endocarditis Valve thrombosis Other

If Aortic Insufficiency, AI Severity¹²¹²⁰: (highest) None Trace/Trivial 1+/Mild 2+/Moderate 3-4+/Severe

If Trace/Trivial, Mild, Moderate, or Severe Perivalvular Severity¹²¹²⁵: None Mild Moderate Severe

If Trace/Trivial, Mild, Moderate, or Severe Central Severity¹²¹³⁰: None Mild Moderate Severe

If Aortic Stenosis, AS Severity¹²¹³⁵: (highest) Possible stenosis Significant stenosis

If Other, Other Indication¹²¹⁴⁰: _____

Clinical Comments¹²¹⁴⁵: (information and details that may assist in assessing this re-intervention)