# TAVR Data Collection Form v2.1

## A. DEMOGRAPHICS

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Middle Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SSN</th>
<th>Patient ID</th>
<th>Other ID</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Birth Date</th>
<th>Sex</th>
<th>Hispanic or Latino Ethnicity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race</th>
<th>Arrival Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## B. EPISODE OF CARE

<table>
<thead>
<tr>
<th>Insurance Payors</th>
<th>HIC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research Study</th>
<th>Study Patient ID</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## C. HISTORY AND RISK FACTORS (PATIENT HISTORY AND RISK FACTORS UP TO THE PROCEDURE)

### CARDIAC HISTORY

**Infected Endocarditis**

- If Yes, Infection Cardiac Valve Type

**Permanent Pacemaker**

- If Yes, Previous Pacer Date

**Previous ICD**

- If Yes, Previous Pacer Date

**Prior PCI**

- If Yes, Most Recent PCI Date

**Prior CABG**

- If Yes, Most Recent CABG Date

**Prior Other Cardiac Surgery**

- # Previous Cardiac Surgeries

### Prior Aortic Valve Procedure

- If Yes, Most Recent AV Procedure Date

### Prior Non-Aortic Valve Procedure

- If Yes, MV Replacement – Surgical

### OTHER HISTORY AND RISK FACTORS

<table>
<thead>
<tr>
<th>Prior Stroke</th>
<th>Hypertension</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Transient Ischemic Attack</th>
<th>Diabetes Mellitus</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Carotid Stenosis</th>
<th>Currently on Dialysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Peripheral Arterial Disease</th>
<th>Hostile Chest</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Current/Recent Smoker</th>
<th>Immunocompromise Present</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
D. PRE-PROCEDURE STATUS (COMPLETE FOR THE PROCEDURE)

<table>
<thead>
<tr>
<th>CAD Presentation</th>
<th>Prior MI</th>
<th>Heart Failure w/ 2 Weeks</th>
<th>NYHA Class w/ 2 Weeks</th>
<th>Cardiogenic Shock w/ 24 Hours</th>
<th>Cardiac Arrest w/ 24 Hours</th>
<th>Cardiac Procedure w/ 30 Days</th>
<th>Porcelain Aorta</th>
<th>Atrial Fibrillation/Flutter</th>
<th>Conduction Defect</th>
<th>Five Meter Walk Test</th>
<th>STS Risk Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>O No Sxs, no angina (14 days)</td>
<td>O No</td>
<td>O No</td>
<td>O I</td>
<td>O No</td>
<td>O No</td>
<td>O No</td>
<td>O No</td>
<td>O No</td>
<td>O No</td>
<td>If Yes, Time 1:</td>
<td></td>
</tr>
<tr>
<td>O Unstable angina (60 days)</td>
<td>O Yes</td>
<td>O Yes</td>
<td>O II</td>
<td>O Yes</td>
<td>O Yes</td>
<td>O Yes</td>
<td>O Yes</td>
<td>O Yes</td>
<td>O Yes</td>
<td>If Yes, Time 2:</td>
<td></td>
</tr>
<tr>
<td>O Sx unlikely to be ischemic (14 days)</td>
<td>O Yes</td>
<td>O Yes</td>
<td>O III</td>
<td>O Yes</td>
<td>O Yes</td>
<td>O Yes</td>
<td>O Yes</td>
<td>O Yes</td>
<td>O Yes</td>
<td>If Yes, Time 3:</td>
<td></td>
</tr>
<tr>
<td>O Non-STEMI (7 days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O Unable to walk:</td>
<td></td>
</tr>
<tr>
<td>O Stable angina (42 days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>O STEMI (7 days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Prior MI Timeframe: O < 30 Days O >= 30 days

Heart Failure w/ 2 Weeks: O No O Yes

NYHA Class w/ 2 Weeks: O I O II O III O IV

Cardiogenic Shock w/ 24 Hours: O No O Yes

Cardiac Arrest w/ 24 Hours: O No O Yes

Cardiac Procedure w/ 30 Days: O No O Yes

Porcelain Aorta: O No O Yes

Atrial Fibrillation/Flutter: O No O Yes

KCCQ-12 Performed: O No O Yes

If Yes, KCCQ-12: Q1a: _______ Q1b: _______ Q1c: _______ Q2: _______ Q3: _______ Q4: _______

(See separate questionnaire)

Q5: _______ Q6: _______ Q7: _______ Q8a: _______ Q8b: _______ Q8c: _______

CLINICAL DATA (CLOSEST TO THE PROCEDURE)

<table>
<thead>
<tr>
<th>Height</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>_______ cm</td>
<td>_______ kg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hemoglobin</th>
<th>Creatinine</th>
<th>Platelet Count</th>
<th>INR</th>
<th>Albumin</th>
<th>Bilirubin</th>
<th>FEV1 Predicted</th>
</tr>
</thead>
<tbody>
<tr>
<td>_______ g/dL</td>
<td>_______ mg/dL</td>
<td>_______ µL</td>
<td></td>
<td>_______ g/dL</td>
<td>_______ mg/dL</td>
<td>_______ %</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Not Drawn</th>
<th>Not Drawn</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>DLCO (Adjusted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>_______ %</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Not Performed</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Not performed</th>
<th>Yes</th>
<th>Unable to walk</th>
</tr>
</thead>
</table>

MEDICATIONS (ADMINISTERED WITHIN 24 HOURS PRIOR TO THE PROCEDURE)

<table>
<thead>
<tr>
<th>Anticoagulants</th>
<th>O No O Yes O Contraindicated O Blinded</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Inotropes</th>
<th>O No O Yes O Contraindicated O Blinded</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Dopamine</th>
<th>Dobutamine</th>
<th>Milrinone</th>
</tr>
</thead>
</table>

DIAGNOSTIC CATH FINDINGS / ECHOCARDIOGRAM FINDINGS

<table>
<thead>
<tr>
<th>Diagnostic Cath</th>
<th>O No O Yes</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>If Yes, Diagnostic Cath Date</th>
<th>mm / dd / yyyy</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Number of Diseased Vessels</th>
<th>Left Vent Internal Systolic Dim</th>
</tr>
</thead>
<tbody>
<tr>
<td>O No O Yes O 1 O 2 O 3</td>
<td>cm</td>
</tr>
</tbody>
</table>

| Left Vent Internal Diastolic Dim | cm | cm |

<table>
<thead>
<tr>
<th>Proximal LAD</th>
<th>Septal Wall Thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td>O No O Yes</td>
<td>cm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Right Ventricular Systolic Pressure</th>
<th>cm</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Left Atrial Volume</th>
<th>mL</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>LA Volume Index</th>
<th>mL/m2</th>
</tr>
</thead>
</table>

AV Disease Etiology

<table>
<thead>
<tr>
<th>O Degenerative</th>
<th>O Endocarditis</th>
<th>O Congenital</th>
<th>O Rheumatic</th>
<th>O Primary aortic disease</th>
</tr>
</thead>
</table>

| O LV outflow tract obstruction | O Supravalvular aortic stenosis | O Tumor | O Trauma | O Other |

Aortic Insufficiency (highest)

| O None | O Trace/Trivial | O 1+/Mild | O 2+/Moderate | O 3-4+/Severe |

Valve Morphology

| O Unicuspid | O Bicuspid | O Tricuspid | O Quadracuspip | O Uncertain |

Annular Calcification

| O No O Yes | |

AV Peak Velocity (CW)

| _______ m/s | |

AV Annulus Size

| _______ mm | |

Annulus Size Assessment Method

| O TTE O TEE O CTA O Angiography |
### Aortic Stenosis

- **AV Area**: (smallest) __________ cm²  
  - If Yes, **AV Mean Gradient**: __________ mmHg  
  - If Yes, **AV Peak Gradient**: __________ mmHg  

### Mitral Valve Disease

- **MV Area**: (smallest) __________ cm²  
  - If Yes, **MV Mean Gradient**: __________ mmHg  

### Tricuspid Insufficiency

- **AV Peak Gradient**: __________ mmHg  
- **Tricuspid Insufficiency**: (highest) O None O Trace/Trivial O Mild O Moderate O Severe

### Mitral Insufficiency

- **Mitral Insufficiency**: (highest) O None O Trace/Trivial O 1+/mild O 2+/moderate O 3+/mod/severe O 4+/severe

### Mitral Stenosis

- **Mitral Stenosis**: O No O Yes

### Tricuspid Insufficiency

- **Tricuspid Insufficiency**: Multiple degrees

### Operator Information

- **Operator A Name**: __________ OPI: __________  
  - **Operator A NPI**: __________  
- **Operator B Name**: __________ OPI: __________  
  - **Operator B NPI**: __________

### Procedure Information

- **Procedure Start Date/Time**: mm/dd/yyyy HH:MM  
  - **Procedure Stop Date/Time**: mm/dd/yyyy HH:MM

### Procedure Location

- **Location**: O Hybrid OR Suite O Hybrid Cath Suite O CathLab O Other

### Procedure Status

- **Status**: O Elective O Urgent O Emergency O Salvage

### Primary Procedure Indication

- **Indication**: O Primary AS O Primary AI O Mixed AS/AI O Failed Bioprosthetic Valve

### Valve-in-Valve Procedure

- **Status**: O Elective O Immediate intraprocedure

### Operator Reason for Procedure

- **Reason**: 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

- **Approval**: O No O Yes

### Procedure Aborted

- **Reason**: O Access related O New clinical findings O System issue O Navigation Issue after successful access O Patient status O Other (not specified)

### Conversion to Open Heart Surgery

- **Reason**: O Valve dislodged to aorta O Anulus rupture O Valve dislodged to left ventricle O Aortic dissection O Ventricular rupture O Coronary occlusion O Other

### Mechanical Assist Device in Place at Start of Procedure

- **Status**: O No O Yes - IABP O Yes - Catheter-based assist device (Impella, Tandem Heart)

### CardioPulmonary Bypass Used

- **Status**: O No O Yes  
  - **CPB Time**: __________ mins

### Type of Anesthesia

- **Anesthesia**: O Moderate sedation O General anesthesia O Epidural O Combination

### Intra-Procedure Medications

- **Inotropes**: (positive) O No O Yes O Contraindicated O Blinded

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Valve Sheath Access Site:
- O Femoral
- O Axillary
- O Transapical
- O Transaortic
- O Subclavian
- O Transiliac
- O Transseptal
- O Transeptal
- O Transcarotid
- O Transcaval
- O Other

Valve Sheath Access Method:
- O Percutaneous
- O Cutdown
- O Mini thoracotomy
- O Mini sternotomy
- O Other

Valve Sheath Delivery Size:
- __________ French

Device 1 Used:
- Refer to Master Device List (code all valves, embolic protection, valve fracture and the BASILICA)

Device 2 Used:
- protection, valve fracture and the BASILICA)

Device Serial Number:
- __________

Device Implantation Method:
- __________

Device Implantation Size:
- __________

Device Implantation Related Event:
- __________

Device Implantation Related Event
- __________

E. Procedure Information – Continued: Post Implant

AV Gradient (mean):
- __________ mmHg

Calculated Aortic Valve Area:
- __________ cm²

Contrast Volume:
- __________ ml

Radiation Dose Measurement Method:
- O Single Plane
- O Biplane

→ Fluoroscopy Time:
- __________ minutes

→ Cumulative Air Kerma:
- __________ mGy

→ Dose Area Product:
- __________

→ Dose Area Product:
- __________ DAP Units:
- 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:
- O No
- O Yes

→ If Yes, specify the Event(s) and Event Date(s):

Myocardial Infarction:
- mm / dd / yyy

Coronary Compression or Obstruction:
- mm / dd / yyy

Endocarditis:
- mm / dd / yyy

Conduction/Native Pacer Disturbance Req Pacer:
- mm / dd / yyy

Conduction/Native Pacer Disturbance Req ICD:
- mm / dd / yyy

Cardiac Arrest:
- mm / dd / yyy

Atrial Fibrillation:
- mm / dd / yyy

Annular Dissection:
- mm / dd / yyy

Aortic Dissection:
- mm / dd / yyy

Perforation with or w/o Tamponade:
- mm / dd / yyy

Transplant Ischemic Attack:
- (complete Adjudication)

Ischemic Stroke:
- (complete Adjudication)

Hemorrhagic Stroke:
- (complete Adjudication)

Undetermined Stroke:
- (complete Adjudication)

Transapical Related Event:
- mm / dd / yyy

Transaortic Related Event:
- mm / dd / yyy

Major Vascular Complication:
- mm / dd / yyy

Minor Vascular Complication:
- mm / dd / yyy

Bleeding at Access Site:
- mm / dd / yyy

Hematoma at Access Site:
- mm / dd / yyy

Retroperitoneal Bleeding:
- mm / dd / yyy

GI Bleed:
- mm / dd / yyy

GU Bleed:
- mm / dd / yyy

Other Bleed:
- mm / dd / yyy

Device Migration:
- mm / dd / yyy

Device Embolization Left Ventricle:
- mm / dd / yyy

Device Embolization Aorta:
- mm / dd / yyy

Device Recapture or Retrieval:
- mm / dd / yyy

Device Thrombosis:
- mm / dd / yyy

Other Device Related Event:
- mm / dd / yyy

New Requirement for Dialysis:
- mm / dd / yyy

Aortic Valve Re-intervention:
- mm / dd / yyy

Unplanned Other Cardiac Surgery or Intervention:
- mm / dd / yyy

Unplanned Vascular Surgery or Intervention:
- mm / dd / yyy

PCI:
- mm / dd / yyy
If TTE, TEE, Mitral Regurgitation 8075:
- None
- Trace/Trivial
- 1+/Mild
- 2+/Moderate
- 3+/Severe
- 4+/Severe

If TTE, TEE, Aortic Stenosis 8080:
- Trace/Trivial
- Mild
- Moderate
- Severe

If TTE, TEE, Date 8070:
- mm / dd / yyyy

If TTE, TEE, Mitral Regurgitation 8075:
- None
- Trace/Trivial
- 1+/Mild
- 2+/Moderate
- 3+/Severe
- 4+/Severe

If TTE, TEE, Aortic Insufficiency Severity 8095:
- Trace/Trivial
- Mild
- Moderate
- Severe
- Not documented

Discharge Date 9045:
- mm / dd / yyyy

Discharge Status 9050:
- Alive
- Deceased

Discharge Location 9055:
- Home
- Extended care/TCU/rehab
- Hospice
- Other acute care hospital
- Nursing home
- Other
- Other acute care hospital
- Other

Primary Cause of Death 9065:
- Cardiac
- Neurologic
- Renal
- Vascular
- Infection
- Valvular
- Pulmonary
- Unknown
- Other

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
### I. Follow-Up (30 Days, 1 Year from Date of Procedure)

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Patient ID</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Reference Procedure Start Date</th>
<th>Other ID</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Assessment Date</th>
<th>mm / dd / yyyy</th>
</tr>
</thead>
</table>

(If the patient has not been discharged at 30 days, capture the 30 day F/U while still in the facility.)

<table>
<thead>
<tr>
<th>Primary Method to Determine Status</th>
<th>O Clinic</th>
<th>O Medical record</th>
<th>O Letter from medical provider</th>
<th>O Phone call to patient/family</th>
<th>O Social Security death master file</th>
<th>O Other</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Status</th>
<th>O Alive</th>
<th>O Deceased</th>
<th>O Lost to follow-up</th>
<th>O Withdrawn</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>If Deceased, Primary Cause of Death</th>
<th>O Cardiac</th>
<th>O Neurologic</th>
<th>O Renal</th>
<th>O Vascular</th>
<th>O Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>O Valvular</td>
<td>O Pulmonary</td>
<td>O Unknown</td>
<td>O Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If Deceased, Date of Death</th>
<th>mm / dd / yyyy</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Hemoglobin</th>
<th>_______ g/dL</th>
<th>□ Not Drawn</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Creatinine</th>
<th>_______ mg/dL</th>
<th>□ Not Drawn</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>NYHA Classification at Follow-up</th>
<th>O I</th>
<th>O II</th>
<th>O III</th>
<th>O IV</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Five Meter Walk</th>
<th>O Not performed</th>
<th>O Yes</th>
<th>O Unable to walk</th>
<th>If Yes, Time 1</th>
<th>10140: ___ sec</th>
<th>Time 2</th>
<th>10145: ___ sec</th>
<th>Time 3</th>
<th>10150: ___ sec</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>12-Lead ECG Findings</th>
<th>O Not performed</th>
<th>O No significant changes</th>
<th>O New changes noted</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>New changes noted, ECG Changes Noted</th>
<th>O Pathological Q-wave or LBBB</th>
<th>O Arrhythmia</th>
<th>O Both</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Echocardiogram</th>
<th>O Not Performed</th>
<th>O Yes - TTE</th>
<th>O Yes - TEE</th>
<th>If TTE, TEE, Date</th>
<th>mm / dd / yyyy</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>TTE, TEE, LVEF</th>
<th>_______ %</th>
<th>□ LVEF Not Assessed</th>
</tr>
</thead>
</table>

| TTE, TEE, Mean Gradient | (highest) _______ mmHg |

<table>
<thead>
<tr>
<th>If TTE, TEE, Aortic Insufficiency Severity</th>
<th>O None</th>
<th>O Trace/Trivial</th>
<th>O 1+/Mild</th>
<th>O 2+/Moderate</th>
<th>O 3-4+/Severe</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>If Trace/Trivial, Mild, Moderate, or Severe Perivalvular Severity</th>
<th>O None</th>
<th>O Mild</th>
<th>O Moderate</th>
<th>O Severe</th>
<th>O Not documented</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>If Trace/Trivial, Mild, Moderate, or Severe Central Severity</th>
<th>O None</th>
<th>O Mild</th>
<th>O Moderate</th>
<th>O Severe</th>
<th>O Not documented</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>KCCQ-12 Performed</th>
<th>O No</th>
<th>O Yes</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>If Yes, KCCQ-12</th>
<th>Q1a: _______</th>
<th>Q1b: _______</th>
<th>Q1c: _______</th>
<th>Q2: _______</th>
<th>Q3: _______</th>
<th>Q4: _______</th>
</tr>
</thead>
</table>

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<tr>
<th>Q5: _______</th>
<th>Q6: _______</th>
<th>Q7: _______</th>
<th>Q8a: _______</th>
<th>Q8b: _______</th>
<th>Q8c: _______</th>
</tr>
</thead>
</table>

(See separate questionnaire)
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

Myocardial Infarction

Endocarditis

Conduction/Native Pacer Disturbance Req Pacer

Conduction/Native Pacer Disturbance Req ICD

Transient Ischemic Attack

Ischemic Stroke

Hemorrhagic Stroke

Undetermined Stroke

Device Fracture

Device Thrombosis

New Requirement for Dialysis

Aortic Valve Re-intervention

Unplanned Other Cardiac Surgery or Intervention

Unplanned Vascular Surgery or Intervention

PCI

Valve Related Readmission

Non-Valve Related Readmission

Major Vascular Complication

Minor Vascular Complication

Transapical Related Event

Major Bleeding Event

Life Threatening Bleeding

FOLLOW-UP MEDICATIONS (MEDICATIONS PRESCRIBED OR TAKEN AT THE TIME OF FOLLOW-UP)

ACE Inhibitor

Warfarin

ARB

Aspirin

Dabigatran

Beta Blocker

Antiarrhythmics

P2Y12

Factor Xa inhibitor

Paperwork Reduction Act Disclosure Statement

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

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:  
→ If Yes, Clinical Presentation 12025:  
O No  
O Yes  
→ 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-INVENTION

Aortic Valve Re-intervention Date 12000:  mm / dd / yyyy  
Aortic Valve Re-intervention Type 12105:  
O Surgical AV Repair/Replacement  
O Balloon Valvuloplasty  
O Transcatheter AVR  
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)