



Mitral Leaflet Clip Data Collection Form v2.1

STS/ACC
TVT Registry

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 : <input type="radio"/> Male <input type="radio"/> Female		Hispanic or Latino Ethnicity ²⁰⁷⁶ : <input type="radio"/> No <input type="radio"/> Yes	
Race : (check all that apply) <input type="checkbox"/> White ²⁰⁷⁰ <input type="checkbox"/> American Indian/Alaskan Native ²⁰⁷³		<input type="checkbox"/> Black/African American ²⁰⁷¹ <input type="checkbox"/> Native Hawaiian/Pacific Islander ²⁰⁷⁴		<input type="checkbox"/> Asian ²⁰⁷²	
Arrival Date/Time ^{3000,3001} : mm / dd / yyyy HH:MM					
Residence ³⁰⁰³ : <input type="radio"/> Home w/no health-aid <input type="radio"/> Home w/health-aid <input type="radio"/> Long-term care <input type="radio"/> Other <input type="radio"/> Not Documented					
Insurance Payors : (check all that apply) <input type="checkbox"/> Private Health Insurance ³⁰⁰⁵ <input type="checkbox"/> Medicare ³⁰⁰⁶ <input type="checkbox"/> Medicaid ³⁰⁰⁷ <input type="checkbox"/> Military Health Care ³⁰⁰⁸ <input type="checkbox"/> State-Specific Plan (non-Medicaid) ³⁰⁰⁹ <input type="checkbox"/> Indian Health Service ³⁰¹⁰ <input type="checkbox"/> Non-US Insurance ³⁰¹¹ <input type="checkbox"/> None ³⁰¹²					
HIC ³⁰¹⁵ :		Research Study ³⁰³⁰ : <input type="radio"/> No <input type="radio"/> Yes If Yes, Study Patient ID ³⁰³² :			
Infective Endocarditis ⁴⁰⁰⁰ : <input type="radio"/> No <input type="radio"/> Yes If Yes, Infective Endocarditis Type ⁴⁰⁰⁵ : <input type="radio"/> Treated <input type="radio"/> Active		Prior Non Aortic Valve Procedure ⁴⁰⁹⁵ : <input type="radio"/> No <input type="radio"/> Yes If Yes, Most Recent MV Procedure Date ⁴⁰⁹⁷ : mm / dd / yyyy If Yes, MV Repair – Surgical ⁴¹¹⁰ : <input type="radio"/> No <input type="radio"/> Yes			
Heart Failure Hospitalization w/in Past Year ⁴⁰⁰⁶ : <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not Documented		If Yes, Mitral Annuloplasty Ring–Surgical ⁴¹¹¹ : <input type="radio"/> No <input type="radio"/> Yes – partial <input type="radio"/> Yes – circumferential <input type="radio"/> Not Documented			
Permanent Pacemaker ⁴⁰¹⁰ : <input type="radio"/> No <input type="radio"/> Yes If Yes, CRT ⁴⁰¹³ : <input type="radio"/> No <input type="radio"/> Yes		If Yes, MV Transcatheter Intervention ⁴¹¹² : <input type="radio"/> No <input type="radio"/> Yes If Yes, Mitral Transcather Type ⁴¹¹³ : <input type="radio"/> Leaflet clip <input type="radio"/> Direct annuloplasty intervention <input type="radio"/> Coronary sinus based intervention <input type="radio"/> Valve-in-native Valve <input type="radio"/> Valve-in-Valve <input type="radio"/> Other			
Previous ICD ⁴⁰¹⁵ : <input type="radio"/> No <input type="radio"/> Yes If Yes, CRT–D ⁴⁰¹⁶ : <input type="radio"/> No <input type="radio"/> Yes		If Yes, Prior Tricuspid Valve Repair/Replacement ⁴¹¹⁸ : <input type="radio"/> No <input type="radio"/> Yes If Yes, Prior Pulmonic Valve Repair/Replacement ⁴¹¹⁹ : <input type="radio"/> No <input type="radio"/> Yes			
Prior PCI ⁴⁰²⁰ : <input type="radio"/> No <input type="radio"/> Yes					
Prior CABG ⁴⁰³⁰ : <input type="radio"/> No <input type="radio"/> Yes					
# Previous Cardiac Surgeries ⁴⁰⁵⁵ : 0 0 0 1 0 2 0 3 0 >=4					
Prior Aortic Valve Procedure ⁴⁰⁶⁰ : <input type="radio"/> No <input type="radio"/> Yes If Yes, AV Replacement – Surgical ⁴⁰⁷⁰ : <input type="radio"/> No <input type="radio"/> Yes If Yes, AV Repair – Surgical ⁴⁰⁸⁰ : <input type="radio"/> No <input type="radio"/> Yes If Yes, AV Transcatheter Valve Replacement ⁴⁰⁹⁰ : <input type="radio"/> No <input type="radio"/> Yes					
Prior Stroke ⁴¹²⁰ : <input type="radio"/> No <input type="radio"/> Yes If Yes, Most Recent Stroke Date ⁴¹²⁵ : mm / dd / yyyy		Diabetes Mellitus ⁴¹⁶⁵ : <input type="radio"/> No <input type="radio"/> Yes If Yes, Diabetes Therapy ⁴¹⁷⁰ : <input type="radio"/> None <input type="radio"/> Diet <input type="radio"/> Oral <input type="radio"/> Insulin <input type="radio"/> Other			
Transient Ischemic Attack ⁴¹³⁰ : <input type="radio"/> No <input type="radio"/> Yes		Currently on Dialysis ⁴¹⁷⁵ : <input type="radio"/> No <input type="radio"/> Yes			
Carotid Stenosis ⁴¹³⁵ : <input type="radio"/> None <input type="radio"/> Right <input type="radio"/> Left <input type="radio"/> Both <input type="radio"/> NA If Yes, Prior CEA/CAS ⁴¹⁴⁰ : <input type="radio"/> No <input type="radio"/> Yes		Chronic Lung Disease ⁴¹⁸⁰ : <input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe			
Peripheral Arterial Disease ⁴¹⁴⁵ : <input type="radio"/> No <input type="radio"/> Yes		Home Oxygen ⁴¹⁸¹ : <input type="radio"/> No <input type="radio"/> Yes			
Current Smoker ⁴¹⁵⁰ (w/in 1 year): <input type="radio"/> No <input type="radio"/> Yes		Hostile Chest ⁴¹⁸² : <input type="radio"/> No <input type="radio"/> Yes			
Hypertension ⁴¹⁵⁵ : <input type="radio"/> No <input type="radio"/> Yes		Immunocompromise Present ⁴¹⁸⁵ : <input type="radio"/> No <input type="radio"/> Yes			



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HOME MEDICATIONS

ACE or ARB (any) ^{4200,4205} :	<input type="radio"/> No <input type="radio"/> Yes	Diuretics – Aldosterone Antagonists ^{4200,4205} :	<input type="radio"/> No <input type="radio"/> Yes
Anticoagulants (any) ^{4200,4205} :	<input type="radio"/> No <input type="radio"/> Yes	Diuretics – Loop diuretic ^{4200,4205} :	<input type="radio"/> No <input type="radio"/> Yes
Aspirin (alone) ^{4200,4205} :	<input type="radio"/> No <input type="radio"/> Yes	If Loop Diuretic, Dose ⁴²¹⁰ : _____ mg	
Aspirin (dual antiplatelet therapy) ^{4200,4205} :	<input type="radio"/> No <input type="radio"/> Yes	Diuretics – Thiazides ^{4200,4205} :	<input type="radio"/> No <input type="radio"/> Yes
Beta Blockers (any) ^{4200,4205} :	<input type="radio"/> No <input type="radio"/> Yes	Diuretics (not otherwise specified) ^{4200,4205} :	<input type="radio"/> No <input type="radio"/> Yes

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

CAD Presentation ⁵⁰⁰⁰ :	<input type="radio"/> No Sxs, no angina (14 days)	<input type="radio"/> Sx unlikely to be ischemic (14 days)	<input type="radio"/> Stable angina (42 days)
	<input type="radio"/> Unstable angina (60 days)	<input type="radio"/> Non-STEMI (7 days)	<input type="radio"/> STEMI (7 days)
Prior MI ⁵⁰⁰⁵ :	<input type="radio"/> No <input type="radio"/> Yes	alf Yes, Prior MI Timeframe ⁵⁰¹⁰ :	<input type="radio"/> < 30 Days <input type="radio"/> >= 30 days
Cardiomyopathy ⁵⁰¹² :	<input type="radio"/> No <input type="radio"/> Yes – Ischemic <input type="radio"/> Yes – Non-ischemic		
Heart Failure w/in 2 Weeks ⁵⁰²⁰ :	<input type="radio"/> No <input type="radio"/> Yes	STS Risk Score (MV replace) ⁵¹⁰⁶ : _____ %	
NYHA Class w/in 2 Weeks ⁵⁰²⁵ :	<input type="radio"/> I <input type="radio"/> II <input type="radio"/> III <input type="radio"/> IV	STS Risk Score (MV repair) ⁵¹⁰⁷ : _____ %	
Cardiogenic Shock w/in 24 Hours ⁵⁰³⁰ :	<input type="radio"/> No <input type="radio"/> Yes	Six Minute Walk Test ⁵¹¹⁵ : <input type="radio"/> Performed <input type="radio"/> Not performed – non-cardiac reason <input type="radio"/> Not performed – cardiac reason <input type="radio"/> Not performed – patient not willing to walk <input type="radio"/> Not performed by site	
Cardiac Arrest w/in 24 Hours ⁵⁰³⁵ :	<input type="radio"/> No <input type="radio"/> Yes		
Porcelain Aorta ⁵⁰⁴⁵ :	<input type="radio"/> No <input type="radio"/> Yes		
Atrial Fibrillation/Flutter ⁵⁰⁵⁰ :	<input type="radio"/> No <input type="radio"/> Yes		
If Yes, AF Class w/in past 30 days ⁵⁰⁵² :	<input type="radio"/> None <input type="radio"/> Persistent <input type="radio"/> Paroxysmal		
Test Date ⁵¹¹⁶ :	mm / dd / yyyy		
Total Distance ⁵¹¹⁷ :	_____ ft		
KCCQ-12 Performed ⁵¹⁶⁹ :	<input type="radio"/> No <input type="radio"/> 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	<input type="checkbox"/> Not Drawn ⁵²⁵¹
Creatinine ⁵²⁵⁵ : _____ mg/dL	<input type="checkbox"/> Not Drawn ⁵²⁵⁶	BNP ⁵²⁷⁷ : _____ pg/mL	(OR) NT proBNP ⁵²⁷⁸ : _____ pg/mL
FEV1 Predicted ⁵²⁸⁰ : _____ %	<input type="checkbox"/> Not Performed ⁵²⁸¹		<input type="checkbox"/> Not Drawn ⁵²⁷⁹
DLCO (Adjusted) ⁵²⁸⁵ : _____ %	<input type="checkbox"/> Not Performed ⁵²⁸⁶	QRS Duration ⁵²⁹⁰ : _____ msec	<input type="checkbox"/> Ventricular Paced ⁵²⁹¹

MEDICATIONS (ADMINISTERED WITHIN 24 HOURS PRIOR TO THE PROCEDURE)

Inotropes^{5400,5405} (positive): No Yes Contraindicated Blinded



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DIAGNOSTIC CATH FINDINGS

Number of Diseased Vessels⁵⁵⁰⁶: None 1 2 3

Left Main Stenosis \geq 50%⁵⁵⁰⁷: No Yes

LVEF⁵⁵⁶⁵: _____ % LVEF Not Assessed⁵⁵⁶⁶

Cardiac Output⁵⁵⁶⁷: _____ L/min Not Performed⁵⁵⁶⁹

Pulmonary Capillary Wedge Pressure⁵⁵⁹⁰: _____ mmHg Not Measured⁵⁵⁹¹

Pulmonary Artery Pressure (mean)⁵⁵⁹³: _____ mmHg Not Measured⁵⁵⁹⁴

Pulmonary Artery Pressure (systolic)⁵⁵⁹⁶: _____ mmHg Not Measured⁵⁵⁹⁷

Right Atrial Pressure/CVP (mean)⁵⁵⁹⁸: _____ mmHg Not Measured⁵⁵⁹⁹

ECHOCARDIOGRAM FINDINGS

Left Ventricular Internal Systolic Dimension⁵⁵⁹⁵: _____ cm Not Measured⁵⁶⁰⁸

Left Ventricular Internal Diastolic Dimension⁵⁶⁰⁰: _____ cm Not Measured⁵⁶⁰⁹

Left Ventricular End Systolic Volume⁵⁶⁰¹: _____ ml Not Measured⁵⁶⁰²

Left Ventricular End Diastolic Volume⁵⁶⁰³: _____ ml Not Measured⁵⁶⁰⁴

Left Atrial Volume⁵⁶⁰⁶: _____ mL (OR) LA Volume Index⁵⁶⁰⁷: _____ mL/m²

Aortic Regurgitation⁵⁶³⁰ (highest): None Trace/Trivial 1+ (mild) 2+ (moderate) 3-4+ (severe)

Aortic Stenosis⁵⁶⁶⁵: No Yes

Mitral Valve Disease⁵⁶⁸⁵: No Yes **If Yes, complete the following:**

Mitral Regurgitation⁵⁶⁹⁵ (highest): None Trace/Trivial 1+ (mild) 2+ (moderate) 3+ (moderate – severe) 4+ (severe)

Note: According to American Society of Echocardiography Guidelines

Effective Orifice Area (EOA) or EROA⁵⁶⁹⁸: _____ cm² Method of Assessment⁵⁶⁹⁹: 3D Planimetry PISA
 Quantitative Doppler Other

Mitral Valve Stenosis⁵⁷⁰⁵: No Yes

MV Area⁵⁷¹⁰: _____ cm² MV Mean Gradient⁵⁷¹⁵ (highest): _____ mmHg

Tricuspid Regurgitation⁵⁷³⁵: None Trace/Trivial Mild Moderate Severe

Mitral Valve Disease Etiology (check all that apply):

Functional Mitral Regurgitation (FMR)⁵⁷⁴⁵ Degenerative Mitral Regurgitation (DMR)⁵⁷⁴⁶ Post – Inflammatory⁵⁷⁴⁷

Endocarditis⁵⁷⁴⁸ Other/Indeterminate⁵⁷⁴⁹

If FMR is Yes, Functional Type⁵⁷⁵⁵:

- Ischemic-acute, post infarction
- Ischemic-chronic
- Non-ischemic dilated cardiomyopathy
- Restrictive cardiomyopathy
- Hypertrophic cardiomyopathy
- Pure annular dilation (w/normal LV systolic fx)
- Not Documented

If DMR is Yes, Leaflet

Prolapse⁵⁷⁶⁰: None Anterior Posterior Bi-leaflet
 Not Documented

If DMR is Yes, Leaflet

Flail⁵⁷⁶⁵: None Anterior Posterior Bi-leaflet
 Not Documented

If Inflammatory is Yes,

Type⁵⁷⁷⁰: Idiopathic Prior radiation Rx Collagen vascular disease
 Drug induced Rheumatic fever history Not Documented



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ECHOCARDIOGRAM FINDINGS

- Mitral Leaflet Calcification**⁵⁸¹⁰: Yes No Not Documented
- Leaflet Tethering**⁵⁷⁷⁵: None Anterior Posterior Bi-leaflet Not Documented
- Mitral Annular Calcification**⁵⁸⁰⁰: Yes No Not Documented
- Carpentier's Functional Class of Mitral Regurgitation**⁵⁸²⁰: Type I Type II Type IIIa Type IIIb Not Documented

LEAFLET CLIP PROCEDURE REASONS/INDICATIONS (CHECK ALL THAT APPLY – AT LEAST ONE INDICATION SHOULD BE SELECTED)

- Frailty**⁵⁹⁰⁰ (assessed by in-person cardiac surgeon consultation) **Hostile Chest**⁵⁹⁰¹
- Severe Liver Disease (Cirrhosis or MELD score >12)**⁵⁹⁰² **Porcelain Aorta**⁵⁹⁰³ (or extensively calcified ascending aorta)
- Predicted STS MV Repair Operative Mortality Risk of >=6%** (for patients deemed likely to undergo MV repair)⁵⁹⁰⁵
- Predicted STS MV Replacement Operative Mort Risk >=8%** (for patients deemed likely to undergo MV replacement)⁵⁹⁰⁴
- Unusual Extenuating Circumstance**⁵⁹⁰⁶ If Unusual Extenuating Circumstance, check all that apply:
- Right Ventricular Dysfunction w/Severe Tricuspid Regurg**⁵⁹⁰⁷ **Chemotherapy for Malignancy**⁵⁹⁰⁸ **Major Bleeding Diathesis**⁵⁹⁰⁹
- Immobility**⁵⁹¹⁰ **AIDS**⁵⁹¹¹ **Severe Dementia**⁵⁹¹² **High Risk of Aspiration**⁵⁹¹³ **IMA at High Risk of Injury**⁵⁹¹⁴
- Other**⁵⁹¹⁵ If Other, Specify⁵⁹¹⁶ (provide reason why patient is prohibitive risk): _____

E. PROCEDURE INFORMATION (COMPLETE FOR EACH LEAFLET CLIP PROCEDURE)

Procedures

- Transcatheter Aortic Valve Replacement**⁶⁶⁰⁰ **Transcatheter Mitral Valve Replacement**⁶⁶⁰¹ **Mitral Leaflet Clip Procedure**⁶⁶⁰²

Other Procedure Performed Concurrently⁶⁶²⁰: No Yes – PCI Yes – Other

Operator A Name^{6000,6005,6010}:

Operator A NPI⁶⁰¹⁵:

Operator B Name^{6020,6025,6030}:

Operator B NPI⁶⁰³⁵:

Procedure Start Date^{6040,6041}: mm / dd / yyyy HH:MM

Procedure Stop Date^{6045,6046}: mm / dd / yyyy HH:MM

Procedure Status⁶⁰⁵⁵: Elective Urgent Emergency Salvage

Type of Anesthesia⁶¹¹⁰: General anesthesia Moderate sedation Epidural Combination

Guiding Cath Access Site⁶²¹²: Right femoral vein Left femoral vein Jugular vein Other vein

Stearable Guide Model ID²⁶¹⁸⁰: _____

Stearable Guide Cath Serial Number²⁶¹⁸²: _____

Leaflet Clip Counter ²⁶²⁴⁰ :	Leaflet Clip #1	Leaflet Clip #2	Leaflet Clip #3
Leaflet Clip Model ID ²⁶²⁴⁵ :	Refer to Device List	Refer to Device List	Refer to Device List
Leaflet Clip Serial # ²⁶²⁵⁰ :			
UDI ^{26255, 26260, 26265}	(future)	(future)	(future)
Location ²⁶²⁷⁰ :	<input type="radio"/> A1P1 <input type="radio"/> A2P2 <input type="radio"/> A3P3	<input type="radio"/> A1P1 <input type="radio"/> A2P2 <input type="radio"/> A3P3	<input type="radio"/> A1P1 <input type="radio"/> A2P2 <input type="radio"/> A3P3
Clip Deployed ²⁶²⁷⁵ :	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
If No, Reason ²⁶²⁸⁰ :	<input type="radio"/> Inability to grasp leaflets <input type="radio"/> Inability to reduce MR <input type="radio"/> Mitral stenosis <input type="radio"/> MV injury <input type="radio"/> Device malfunction <input type="radio"/> Adverse event <input type="radio"/> Other	<input type="radio"/> Inability to grasp leaflets <input type="radio"/> Inability to reduce MR <input type="radio"/> Mitral stenosis <input type="radio"/> MV injury <input type="radio"/> Device malfunction <input type="radio"/> Adverse event <input type="radio"/> Other	<input type="radio"/> Inability to grasp leaflets <input type="radio"/> Inability to reduce MR <input type="radio"/> Mitral stenosis <input type="radio"/> MV injury <input type="radio"/> Device malfunction <input type="radio"/> Adverse event <input type="radio"/> Other



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POST IMPLANT

Mitral Regurgitation²⁶²⁸⁵: None Trace/Trivial 1+ (mild) 2+ (moderate) 3+ (moderate – severe) 4+ (severe)

Note: According to American Society of Echocardiography Guidelines

MV Mean Gradient²⁶²⁹⁰: _____ mmHg

Conversion to Open Heart Surgery²⁶¹⁰⁵: No Yes

Mechanical Assist Device²⁶¹⁴⁰: No Yes

If Yes, **Timing**²⁶¹⁴¹: Pre-procedure Intra-procedure Post-procedure

If Yes, **Type**²⁶¹⁴²: IABP Catheter-based assist device

Cardiopulmonary Bypass Used⁶¹⁰⁰: No Yes

If Yes, **Status**⁶¹⁰¹: Elective Emergent If Yes, **CPB Time**⁶¹⁰⁵: _____ mins

Radiation Dose Measurement Method⁶⁴⁵⁵: Single Plane Biplane

Fluoroscopy Time⁶⁴⁶⁰: _____ mins **Cumulative Air Kerma**⁶⁴⁶⁵: _____ mGy

Dose Area Product⁶⁴⁷⁰: _____ **DAP Units**⁶⁴⁷⁵: Gy-cm² cGy-cm² mGy-cm² μGy-M²

Procedure Duration	Start Time	Stop Time
Procedure Room	Arrival Date/Time ^{26060,26061} mm / dd / yyyy HH:MM	
Anesthesia	Induction ²⁶⁰⁷⁰ HH:MM	Discontinuation ²⁶⁰⁷¹ HH:MM
Procedure Access	Vascular or TEE Access ²⁶⁰⁷⁵ HH:MM	Last Cath/TEE Removed ²⁶⁰⁷⁶ HH:MM
Transseptal Access	Transseptal Access ²⁶⁰⁸⁰ HH:MM	Septum Crossed ²⁶⁰⁸¹ HH:MM
Device	SCG in Intra-atrial Septum ²⁶⁰⁸⁶ HH:MM	Delivery System Retracted ²⁶⁰⁹¹ HH:MM
		SCG Device Removal (from fem vein) ²⁶⁰⁹⁶ HH:MM

F. ADVERSE EVENTS, INTERVENTIONS AND SURGERIES (COMPLETE FOR EACH PROCEDURE. SPECIFY EVENT DATE FOR EACH EVENT OCCURRENCE.)

Intra or Post Procedure Events Occurred⁷³⁰⁰: No Yes If Yes, specify the **Event**⁷³⁰¹ and **Event Date(s)**⁷³⁰²:

System	Event	Date	
Cardiac	Atrial Fibrillation (new onset) ^{E006} :	mm / dd / yyyy	
	Cardiac Arrest ^{E005} :	mm / dd / yyyy	
	Endocarditis ^{E003} :	mm / dd / yyyy	
	Myocardial Infarction ^{E059} :	mm / dd / yyyy	
	Perforation (w/ or w/o Tamponade) ^{E009} :	mm / dd / yyyy	
Valve	Mitral Leaflet Injury (detected during surgery) ^{E045} :	mm / dd / yyyy	
	Mitral Leaflet Injury (ascertained by echo) ^{E046} :	mm / dd / yyyy	
	Mitral Subvalvular Injury (detected during surgery) ^{E047} :	mm / dd / yyyy	
	Mitral Subvalvular Injury (ascertained by echo) ^{E048} :	mm / dd / yyyy	
Renal	New Requirement for Dialysis ^{E029} :	mm / dd / yyyy	
	Neuro	Transient Ischemic Attack ^{E010} (complete Adjudication):	mm / dd / yyyy
		Ischemic Stroke ^{E011} (complete Adjudication):	mm / dd / yyyy
		Hemorrhagic Stroke ^{E012} (complete Adjudication):	mm / dd / yyyy
		Stroke (Undetermined Type) ^{E013} (complete Adjudication):	mm / dd / yyyy
		Single Leaflet Device Attachment ^{E049} :	mm / dd / yyyy
		Complete Detachment of Leaflet Clip (from valve leaflets) ^{E051} :	mm / dd / yyyy
Device Embolization ^{E050} :	mm / dd / yyyy		
Device/Delivery System	Delivery system component embolization ^{E058} :	mm / dd / yyyy	
	Device Thrombosis ^{E027} :	mm / dd / yyyy	
	Other Device/Delivery System Related Event ^{E028} :	mm / dd / yyyy	



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F. ADVERSE EVENTS, INTERVENTIONS AND SURGERIES (COMPLETE FOR EACH PROCEDURE. SPECIFY EVENT DATE FOR EACH EVENT OCCURRENCE.)

Intra or Post Procedure Events Occurred⁷³⁰⁰: No Yes If Yes, specify the Event⁷³⁰¹ and Event Date(s)⁷³⁰²:

Bleed/Vascular	Bleeding at Access Site ^{E017} : _____ mm / dd / yyyy	Vascular	Major Vascular Complication ^{E041} : _____ mm / dd / yyyy
	Hematoma at Access Site ^{E018} : _____ mm / dd / yyyy		Minor Vascular Complication ^{E042} : _____ mm / dd / yyyy
	Retroperitoneal Bleeding ^{E019} : _____ mm / dd / yyyy		
	GI Bleed ^{E020} : _____ mm / dd / yyyy	Additional Procedures	Mitral Valve Re-intervention ^{E053} (complete Adjudication): _____ mm / dd / yyyy
	GU Bleed ^{E021} : _____ mm / dd / yyyy		Unplanned Other Cardiac Surgery or Intervention ^{E031} (not MVR): _____ mm / dd / yyyy
	Other Bleed ^{E022} : _____ mm / dd / yyyy		Unplanned Vascular Surgery or Intervention ^{E032} (for Bleeding or Access Site Complication): _____ mm / dd / yyyy
	Transseptal Complication ^{E052} : _____ mm / dd / yyyy		ASD Closure Due To Transseptal Catheterization ^{E054} : _____ mm / dd / yyyy

G. POST-PROCEDURE LABS AND TESTS

Lowest Hemoglobin⁸⁰⁴⁰: _____ g/dL Not Drawn⁸⁰⁴¹ **Highest Creatinine**⁸⁰⁵⁰: _____ mg/dL Not Drawn⁸⁰⁵¹

Echocardiogram⁸⁰⁶⁵: Not Performed Yes - TTE Yes - TEE If Yes, complete the following:

Date⁸⁰⁷⁰: mm / dd / yyyy

Mitral Regurgitation⁸⁰⁷⁵: None Trace/Trivial 1+ (mild) 2+ (moderate) 3+ (moderate – severe) 4+ (severe)

Note: According to American Society of Echocardiography Guidelines

Effective Orifice Area (EOA) or EROA⁸¹²²: _____ cm² **Method of Assessment**⁸¹²⁵: 3D Planimetry PISA

Mean Mitral Gradient⁸¹³⁰: _____ mmHg Quantitative Doppler Other

H. DISCHARGE (COMPLETE FOR EACH EPISODE OF CARE)

RBC/Whole Blood Transfusion⁹⁰¹¹: No Yes If Yes, # **Units Transfused**⁹⁰¹²: _____ *Note: Code the total # of units between start of the procedure and discharge*

Number of Hours in ICU⁹⁰⁴⁰: _____

Discharge Date⁹⁰⁴⁵: mm / dd / yyyy **Discharge Status**⁹⁰⁵⁰: Alive Deceased

If Alive, **Discharge Location**⁹⁰⁵⁵: Home Extended care/TCU/rehab Other acute care hospital
 Nursing home Hospice Other Left against medical advice (AMA)

If Deceased, **Death in Lab/OR**⁹⁰⁶⁰: No Yes

If Deceased, **Primary Cause of Death**⁹⁰⁶⁵: Cardiac Neurologic Renal Vascular Infection
 Valvular Pulmonary Unknown Other

DISCHARGE MEDICATIONS (NOT REQUIRED FOR PTS WHO EXPIRED OR WERE DISCHARGED TO 'OTHER ACUTE CARE HOSPITAL', 'HOSPICE', OR 'AMA')

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

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

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

Aspirin (dual antiplatelet therapy)^{9100,9105}: No Yes Contraindicated Blinded

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

Diuretics – Aldosterone Antagonists^{9100,9105}: No Yes Contraindicated Blinded

Diuretics – Loop^{9100,9105}: No Yes Contraindicated Blinded

If Loop Diuretic, **Dose**⁹¹¹⁰: _____ mg

Diuretics (not otherwise specified)^{9100,9105}: No Yes Contraindicated Blinded

Diuretics – Thiazides^{9100,9105}: No Yes Contraindicated Blinded



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

Last Name²⁰⁰⁰: _____ **First Name**²⁰¹⁰: _____ **Patient ID**²⁰⁴⁰: _____
Reference Procedure Start Date⁶⁰⁴⁰: mm / dd / yyyy **Other ID**²⁰⁴⁵: _____ **Study Patient ID**³⁰³²: _____ (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

Residence¹⁰⁰⁰⁸: Home w/no health-aid Home w/health-aid Long-term care Other Not documented

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 **Creatinine**¹⁰⁰⁹⁰: _____ mg/dL Not Drawn¹⁰⁰⁹¹

NYHA Classification at Follow-up¹⁰¹⁰⁰: I II III IV

Echocardiogram¹⁰²⁰⁶: Not Performed Yes - TTE Yes - TEE **If Yes, complete the following**

Date¹⁰²⁰⁷: mm / dd / yyyy

LVEF¹⁰²¹⁰: _____ % LVEF Not Assessed¹⁰²¹¹

Mitral Regurgitation¹⁰³⁰⁰: None Trace/Trivial 1+ (mild) 2+ (moderate) 3+ (moderate – severe) 4+ (severe)

Note: According to American Society of Echocardiography Guidelines

Effective Orifice Area (EOA) or EROA¹⁰³¹⁵: _____ cm² **Method of Assessment**¹⁰³²⁰: 3D Planimetry PISA
 Quantitative Dopplar Other

Mean Mitral Gradient¹⁰³³⁰: _____ mmHg

Left Atrial Volume¹⁰³³⁵: _____ mL (OR) **LA Volume Index**¹⁰³⁴⁰: _____ mL/m²

Left Ventricular Internal Systolic Dimension¹⁰³⁴⁵: _____ cm Not Measured¹⁰³⁴⁶

Left Ventricular Internal Diastolic Dimension¹⁰³⁵⁰: _____ cm Not Measured¹⁰³⁵¹

Left Ventricular End Systolic Volume¹⁰³⁵⁵: _____ mL Not measured¹⁰³⁵⁶

Left Ventricular End Diastolic Volume¹⁰³⁶⁰: _____ mL Not measured¹⁰³⁶¹

Tricuspid Regurgitation¹⁰³⁶⁵: None Trace/Trivial Mild Moderate Severe

KCCQ-12 Performed¹⁰²³⁰: No Yes

If Yes, KCCQ-12¹⁰²³¹⁻¹⁰²⁴³: **Q1a:** _____ **Q1b:** _____ **Q1c:** _____ **Q2:** _____ **Q3:** _____ **Q4:** _____

(See separate questionnaire)

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

Six Minute Walk Test Performed¹⁰³⁸⁰: Performed
 Not performed – non-cardiac reason
 Not performed – cardiac reason
 Not performed – patient not willing to walk
 Not performed by site

Test Date¹⁰³⁸⁵: mm / dd / yyyy

Total Distance Walked¹⁰³⁹⁰: _____ ft



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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 Events Occurred ¹⁰²⁴⁵ :		O No	O Yes	If Yes, specify the Event ¹⁰²⁴⁶ and Event Date(s) ¹⁰²⁴⁷ :		
Cardiac	Atrial Fibrillation (new onset) ^{E006} :	mm / dd / yyyy		Bleeding/Vascular	Major Vascular Complication ^{E041} :	mm / dd / yyyy
	Endocarditis ^{E003} :	mm / dd / yyyy			Minor Vascular Complication ^{E042} :	mm / dd / yyyy
	Myocardial Infarction ^{E059} :	mm / dd / yyyy			Major Bleeding Event ^{E043} :	mm / dd / yyyy
Neuro	Transient Ischemic Attack ^{E010} (complete Adjudication):	mm / dd / yyyy		Additional Procedures	Life Threatening Bleeding ^{E037} :	mm / dd / yyyy
	Ischemic Stroke ^{E011} (complete Adjudication):	mm / dd / yyyy			Mitral Valve Re-intervention ^{E053} (complete Adjudication):	mm / dd / yyyy
	Hemorrhagic Stroke ^{E012} (complete Adjudication):	mm / dd / yyyy			ASD Closure Due To Transeptal Catheterization ^{E054} :	mm / dd / yyyy
	Stroke (Undetermined Type) ^{E013} (complete Adjudication):	mm / dd / yyyy			Unplanned Other Cardiac Surgery or Intervention ^{E031} (not Mitral):	mm / dd / yyyy
Device	Device Embolization ^{E050} :	mm / dd / yyyy		Readmission	Unplanned Vascular Surgery or Intervention ^{E032} (for Bleeding or Access Site Complication):	mm / dd / yyyy
	Single Leaflet Device Attachment ^{E049} :	mm / dd / yyyy			Readmission – Heart Failure ^{E055} (complete Adjudication):	mm / dd / yyyy
	Device Thrombosis ^{E027} :	mm / dd / yyyy			Readmission – Cardiac (not HF) ^{E056} :	mm / dd / yyyy
	Other Device Related Event ^{E028} :	mm / dd / yyyy			Readmission – Non-Cardiac (Follow Up) ^{E057} :	mm / dd / yyyy
Renal	New Requirement for Dialysis ^{E029} :	mm / dd / yyyy				

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

ACE/ARB ^{10250,10255} (any):	O No	O Yes	O Contraindicated	O Blinded
Beta Blockers ^{10250,10255} (any):	O No	O Yes	O Contraindicated	O Blinded
Anticoagulants ^{10250,10255} (any):	O No	O Yes	O Contraindicated	O Blinded
Aspirin ^{10250,10255} (alone):	O No	O Yes	O Contraindicated	O Blinded
Aspirin (dual antiplatelet therapy) ^{10250,10255} :	O No	O Yes	O Contraindicated	O Blinded
Diuretics – Aldosterone Antagonists ^{10250,10255} :	O No	O Yes	O Contraindicated	O Blinded
Diuretics – Loop ^{10250,10255} :	O No	O Yes	O Contraindicated	O Blinded
If Loop Diuretic, Dose ¹⁰²⁵⁷ : _____ mg				
Diuretics (not otherwise specified) ^{10250,10255} :	O No	O Yes	O Contraindicated	O Blinded
Diuretics – Thiazides ^{10250,10255} :	O No	O Yes	O Contraindicated	O Blinded



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J. ADJUDICATION FORM (COMPLETE FOR EACH STROKE, TIA, MITRAL VALVE RE-INTERVENTION, OR HEART FAILURE READMISSION)

Last Name²⁰⁰⁰: _____ **First Name**²⁰¹⁰: _____ **Patient ID**²⁰⁴⁰: _____

Reference Procedure Start Date⁶⁰⁴⁰: mm / dd / yyyy **Other ID**²⁰⁴⁵: _____ **Study Patient ID**³⁰³²: (optional) _____

Adjudication Event¹²⁰⁰⁰: Ischemic Stroke(In-hospital) Hemorrhagic Stroke(In-hospital) Undetermined Stroke(In-hospital) TIA(In-hospital)
 Mitral Valve Re-intervention(In-hospital)
 Ischemic Stroke(F-U) Hemorrhagic Stroke(F-U) Undetermined Stroke(F-U) TIA(F-U)
 Mitral Valve Reintervention(F-U)
 Readmission – Heart Failure (F-U)

Event Date¹²⁰⁰⁵: mm / dd / yyyy

Status¹²⁰¹⁰: Alive Deceased **If Deceased, Date of Death**¹²⁰¹¹: mm / dd / yyyy

IF EVENT¹²⁰⁰⁰ IS 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 IS MITRAL VALVE RE-INTERVENTION

Mitral Valve Re-intervention Type¹²²⁰⁰: Surgical MV Repair Surgical MV Replacement Transcatheter MV Repair
 Transcatheter MV Replacement Leaflet Clip Procedure Other Transcath Intervention

If Other Transcatheter Intervention, Other Type¹²²⁰⁵: _____

MV Reintervention Indication¹²²¹⁰: Mitral regurgitation Mitral stenosis Mitral valve injury Other
 Device embolization Endocarditis Device thrombosis

If Other, Other Indication¹²²¹⁵: _____

Clinical Comments¹²²²⁰(information and details that may assist in assessing this re-intervention):

IF EVENT¹²⁰⁰⁰ IS READMISSION (HEART FAILURE)

Hospitalization ≥ 24 hours¹²²²⁵: No Yes Information not available

Clinical Signs and/or Symptoms of Heart Failure¹²²³⁰: No Yes Information not available

IV or Invasive Treatment Required¹²³³⁵: No Yes Information not available

Note: IV includes diuretics or vasoactive therapy and Invasive includes ultrafiltration, IABP, or mechanical assistance