



Transcatheter Mitral Leaflet Clip Procedure (TMVr) v3 Data Collection Form

STS/ACC
TVT Registry™

A. DEMOGRAPHICS

Last Name ²⁰⁰⁰ :	First Name ²⁰¹⁰ :	Middle Name ²⁰²⁰ :
Birth Date ²⁰⁵⁰ : mm / dd / yyyy	SSN ²⁰³⁰ : - - □ SSN N/A ²⁰³¹	Patient ID ²⁰⁴⁰ : (auto)
Other ID ²⁰⁴⁵ :	Sex ²⁰⁶⁰ : ☐ Male ☐ Female	Patient Zip Code ²⁰⁶⁵ : □ Zip Code N/A ²⁰⁶⁶
Race: (check all that apply) ☐ White ²⁰⁷⁰ ☐ Black/African American ²⁰⁷¹ ☐ American Indian/Alaskan Native ²⁰⁷³ ☐ Asian ²⁰⁷² → If Yes, ☐ Asian Indian ²⁰⁸⁰ ☐ Chinese ²⁰⁸¹ ☐ Filipino ²⁰⁸² ☐ Japanese ²⁰⁸³ ☐ Korean ²⁰⁸⁴ ☐ Vietnamese ²⁰⁸⁵ ☐ Other ²⁰⁸⁶ ☐ Native Hawaiian/Pacific Islander ²⁰⁷⁴ → If Yes, ☐ Native Hawaiian ²⁰⁹⁰ ☐ Guamanian or Chamorro ²⁰⁹¹ ☐ Samoan ²⁰⁹² ☐ Other Island ²⁰⁹³		
Hispanic or Latino Ethnicity ²⁰⁷⁶ : ☐ No ☐ Yes → If Yes, Ethnicity Type: (check all that apply) ☐ Mexican, Mexican-American, Chicano ²¹⁰⁰ ☐ Puerto Rican ²¹⁰¹ ☐ Cuban ²¹⁰² ☐ Other Hispanic, Latino or Spanish Origin ²¹⁰³		

B. EPISODE OF CARE

Arrival Date/Time ³⁰⁰¹ : mm / dd / yyyy / hh:mm
Admitting Provider's Name, NPI ^{3050,3051,3052,3053} : Last Name, First Name, MI, NPI
Attending Provider's Name, NPI ^{3055,3056,3057,3058} : Last Name, First Name, MI, NPI, Last Name, First Name, MI, NPI
Health Insurance ³⁰⁰⁵ : ☐ No ☐ Yes → If Yes, Payment Source ³⁰¹⁰ : (Select all that apply) ☐ Private Health Insurance ☐ Medicare (Fee-For-Service) ☐ Medicare Advantage ☐ Medicaid ☐ Military Health Care ☐ State-Specific Plan (non-Medicaid) ☐ Indian Health Service ☐ Non-US Insurance
MBI # ¹²⁸⁴⁶ :
Residence ¹³⁸⁰³ : ☐ Home with No Health Aid ☐ Home with Health Aid ☐ Long Term Care ☐ Other □ Not Documented ¹³⁸⁰⁴

RESEARCH STUDY

Patient Enrolled in Research Study ³⁰²⁰ : ☐ No ☐ Yes → If Yes, Research Study Name ³⁰²⁵ , Research Study Patient ID ³⁰³⁰ : _____, _____	☐ Patient Restriction ³⁰³⁵
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TRANSCATHETER VALVE THERAPY (TVT) PATHWAY

TVT Pathway ¹³¹⁷¹ : ☐ TAVR ☐ TMVr ☐ TMVR ☐ Tricuspid Valve Procedure
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Basic dataset

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C. HISTORY AND RISK FACTORS

Height⁶⁰⁰⁰: _____ cm **Weight**⁶⁰⁰⁵: _____ kg

Number of Prior Open Heart Cardiac Surgeries¹³⁶⁹⁷: _____ (If the patient has had >4 prior surgeries and the number is not known, code 4 prior surgeries)

Heart Failure Hospitalization Within Past Year¹³⁷⁰⁷: ☐ No ☐ Yes ☐ Not Documented¹⁴²⁵³

Oxygen at Home¹³⁸⁸¹: ☐ No ☐ Yes

Immunocompromise Present¹³⁸⁸²: ☐ No ☐ Yes **Currently on Dialysis**¹³⁸⁸⁰ ☐ No ☐ Yes

Tobacco Use⁴⁶²⁵: ☐ Never ☐ Former ☐ Current-Every Day ☐ Current-Some Days ☐ Smoker – Current Status Unk ☐ Unk if ever smoked

→If any Current, **Tobacco Type**⁴⁶²⁶ (Select all that apply): ☐ Cigarettes ☐ Cigars ☐ Pipe ☐ Smokeless

→If Current Every Day and Cigarettes, **Amount**⁴⁶²⁷: ☐ Light tobacco use (<10/day) ☐ Heavy tobacco use (≥10/day)

HOME MEDICATIONS

CATEGORY	MEDICATION CODE ¹²²⁹⁷	MED PRESCRIBED ¹³⁹⁰³	LOOP DIURETIC DOSE ¹⁴⁵⁷⁵
ACE Inhibitors (Angiotensin Converting Enzyme)	Angiotensin Converting Enzyme Inhibitor	☐ No ☐ Yes	
Aldosterone Antagonist	Aldosterone Antagonist	☐ No ☐ Yes	
Angiotensin Receptor-Neprilysin Inhibitor	Angiotensin Receptor-Neprilysin Inhibitor	☐ No ☐ Yes	
Anticoagulant	Anticoagulant	☐ No ☐ Yes	
Antiplatelet	Aspirin	☐ No ☐ Yes	
ARB (Angiotensin Receptors Blockers)	Angiotensin II Receptor Blocker	☐ No ☐ Yes	
Beta Blockers	Beta Blocker	☐ No ☐ Yes	
Diuretics	Diuretics Not Otherwise Specified	☐ No ☐ Yes	
	Loop Diuretics	☐ No ☐ Yes	_____ mg
	Thiazides	☐ No ☐ Yes	
P2Y12 Inhibitors	P2Y12 Antagonist	☐ No ☐ Yes	
Selective Sinus Node I/f Channel Inhibitor	Selective Sinus Node I/f Channel Inhibitor	☐ No ☐ Yes	



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D. LAB VISIT (COMPLETE FOR EACH LAB VISIT)

Procedures¹⁴²⁷³: ☐ TAVR ☐ TMVr ☐ TMVR ☐ Tricuspid Valve Procedure

→ If Mitral Repair, Mitral Leaflet Clip¹³⁷⁹³ ☐ No ☐ Yes

Procedure Room Entry Date/Time¹³³²⁹: mm / dd / yyyy HH:MM Procedure Start Date/Time⁷⁰⁰⁰: mm / dd / yyyy HH:MM

Procedure End Date/Time⁷⁰⁰⁵: mm / dd / yyyy HH:MM Procedure Room Exit Date/Time¹³³³⁰: mm / dd / yyyy HH:MM

PRESENTATION AND EVALUATION

CAD Presentation¹²¹⁷⁷: ☐ No Symptoms, No Angina ☐ Symptoms Unlikely to be Ischemic ☐ Stable Angina
☐ Unstable Angina ☐ Non-STEMI ☐ STEMI

Heart Failure (w/in 2 weeks)¹⁴²⁶⁶: ☐ No ☐ Yes

NYHA Class (w/in 2 weeks)¹²¹⁶³: ☐ I ☐ II ☐ III ☐ IV

Cardiogenic Shock (w/in 24 hrs)¹³¹⁷⁵: ☐ No ☐ Yes

Cardiac Arrest (w/in 24 hrs)¹⁴²⁶⁷: ☐ No ☐ Yes

STS Risk Score Type¹³⁶⁹⁸: STS Risk Score Measurement¹⁴²⁷¹:

MV Repair: _____ %

MV Replace: _____ %

Shared Decision Making¹⁴⁷³²: ☐ No ☐ Yes

→ If Yes, Shared Decision Making Tool Used¹⁴⁷³³: ☐ No ☐ Yes

→ If Yes, Shared Decision Making Tool Name¹⁴⁷³⁴: _____

KCCQ-12 Performed¹³⁸⁴³: ☐ No ☐ Yes

→ If Yes, KCCQ-12^{13846, 48, 49, 51, 53, 55, 57, 59, 61, 63, 65, 67}: (see separate questionnaire)

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

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

KCCQ Summary
Score¹⁴³¹⁰: (calculated) _____

Six Minute Walk Test¹³⁷¹⁰: ☐ No ☐ Yes → If Yes, Test Date¹³⁷¹¹: mm / dd / yyyy → If Yes, Total Distance¹³⁷¹²: _____ ft

→ If No, Reason¹⁴²⁶²: ☐ Non-Cardiac Reason ☐ Cardiac Reason ☐ Patient Not Willing to Walk ☐ Not Performed By Site

PRE-PROCEDURE CLINICAL DATA (CLOSEST TO THE PROCEDURE)

Hemoglobin⁶⁰³⁰: _____ g/dL ☐ Not Drawn⁶⁰³¹ BNP¹⁴²⁸⁰: _____ pg/mL ☐ Not Performed¹³²⁰⁵

Sodium⁶⁰³⁵: _____ mEq/L ☐ Not Drawn⁶⁰³⁶ NT proBNP¹⁴²⁷⁹: (or) _____ pg/mL ☐ Not Performed¹³²⁰⁶

Creatinine⁶⁰⁵⁰: _____ mg/dL ☐ Not Drawn⁶⁰⁵¹

PRE-PROCEDURE ECG AND PULMONARY FUNCTION (CLOSEST TO THE PROCEDURE)

QRS Duration⁵⁰⁵⁵: _____ msec ☐ Ventricular Paced⁵⁰⁴⁵

FEV1 Predicted¹³²¹⁶: _____ % ☐ Not Performed¹³²¹⁷

DLCO (Predicted)¹³²¹⁸: _____ % ☐ Not Performed¹³²¹⁹

PRE-PROCEDURE MEDICATIONS (24 HOURS PRIOR TO THE PROCEDURE)

Positive Inotropes¹³⁶⁴³: ☐ No ☐ Yes

PRE-PROCEDURE DIAGNOSTIC CATH FINDINGS

Diagnostic Cath Performed¹³²²⁰: ☐ No ☐ Yes → If Yes, Diagnostic Cath Date¹³²²²: mm / dd / yyyy

Number of Diseased Vessels¹³³⁸¹: ☐ None ☐ One ☐ Two ☐ Three ☐ Not Documented¹³³⁸²

Left Main Stenosis $\geq$ 50%¹³²⁶⁰: ☐ No ☐ Yes ☐ Not Documented¹³²⁶¹

Proximal LAD $\geq$ 70%¹³³⁰¹: ☐ No ☐ Yes ☐ Not Documented¹³³⁰²

Cardiac Output¹³⁷¹³: _____ L/min ☐ Not Documented¹³⁷¹⁴

Pulmonary Capillary Wedge Pressure¹³⁷¹⁵: _____ mm Hg ☐ Not Documented¹³⁷¹⁶

Pulmonary Artery Pressure (mean)¹³⁷¹⁹: _____ mm Hg ☐ Not Documented¹³⁷²⁰

Pulmonary Artery Pressure (systolic)¹³⁷¹⁷: _____ mm Hg ☐ Not Documented¹³⁷¹⁸

Right Atrial Pressure (mean)¹⁴²⁷²: _____ mm Hg ☐ Not Documented¹³⁸²⁹



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PRE-PROCEDURE ECHOCARDIOGRAM FINDINGS

LVEF ¹³³⁰⁵ : _____ %	☐ LVEF Not Assessed ¹³³⁰⁶
Left Ventricular Internal Systolic Dimension ¹³⁷²¹ : _____ cm	☐ Not Measured ¹³⁷²²
Left Ventricular Internal Diastolic Dimension ¹³⁷²³ : _____ cm	☐ Not Measured ¹³⁷²⁴
Left Ventricular End Systolic Volume ¹³⁷²⁵ : _____ mL	☐ Not Measured ¹³⁷²⁷
Left Ventricular End Diastolic Volume ¹³⁷²⁶ : _____ mL	☐ Not Measured ¹³⁷²⁸
Left Atrial Volume ¹³⁷²⁹ : _____ mL	☐ Not Measured ¹³⁷³⁰ (OR) LA Volume Index ¹³⁷³¹ : _____ mL/m ² ☐ Not Measured ¹³⁷³²
Aortic Regurgitation ¹³⁴⁷⁷ : (highest) ☐ None ☐ Trace/Trivial ☐ Mild ☐ Moderate ☐ Severe	
Aortic Stenosis ¹³³⁰⁷ : ☐ No ☐ Yes	
Mitral Valve Disease ¹³⁷⁰⁴ : ☐ No ☐ Yes	
→If Yes, Mitral Regurgitation ¹³⁶⁷² : (highest) ☐ None ☐ Trace/Trivial ☐ Mild ☐ Moderate ☐ Moderate-Severe ☐ Severe	
→If Yes, Effective Regurgitant Orifice Area (EROA) ¹³⁷³⁷ : _____ cm ²	→If EROA, Method of Assessment ¹³⁷³⁸ : ☐ 3D Planimetry ☐ PISA ☐ Quantitative Dopplar ☐ Other
→If Yes, Mitral Stenosis ¹³³⁰⁸ : ☐ No ☐ Yes	
→If Yes, MV Area ¹³³¹⁶ : (smallest) _____ cm ² (required only if mitral stenosis=yes)	
→If Yes, MV Mean Gradient ¹³³¹⁷ : (highest) _____ mm Hg (required only if mitral stenosis=yes)	
Mitral Valve Disease Etiology ¹³⁴⁹⁰ (Check all that apply): ☐ Functional MR (Secondary) ☐ Degenerative MR (Primary) ☐ Post Inflammatory ☐ Endocarditis ☐ Other ☐ None	
→If Functional, Functional Type ¹³⁷⁴⁰ : ☐ Ischemic Acute, Post Infarction ☐ Ischemic Chronic ☐ Non-Ischemic Dilated Cardiomyopathy ☐ Restrictive Cardiomyopathy ☐ Hypertrophic Cardiomyopathy ☐ Pure Annular Dilation (w/Normal LV Systolic Fx) ☐ Not Documented ¹³⁷⁴¹	
→If Degenerative, Leaflet Prolapse ¹³⁷⁴² : ☐ None ☐ Anterior ☐ Posterior ☐ Bileaflet ☐ Not Documented ¹³⁷⁴⁵	
→If Degenerative, Leaflet Flail ¹³⁷⁴³ : ☐ None ☐ Anterior ☐ Posterior ☐ Bileaflet ☐ Not Documented ¹³⁷⁴⁶	
→If Inflammatory, Type ¹³⁷⁴⁸ : ☐ Collagen Vascular Disease ☐ Drug Induced ☐ Idiopathic ☐ Prior Radiation Therapy ☐ Rheumatic Fever ☐ Not Documented ¹³⁷⁵³	
Leaflet Tethering ¹³⁷⁴⁴ : ☐ None ☐ Anterior ☐ Posterior ☐ Bileaflet ☐ Not Documented ¹³⁷⁴⁷	
Mitral Valve Annular Calcification ¹³⁷⁴⁹ : ☐ No ☐ Yes ☐ Not Documented ¹³⁷⁵⁰	
Mitral Leaflet Calcification ¹³⁷⁵¹ : ☐ Yes ☐ No ☐ Not Documented ¹³⁷⁵²	
Tricuspid Regurgitation ¹³³¹⁸ : (highest) ☐ None ☐ Trace/Trivial ☐ Mild ☐ Moderate ☐ Severe	

PROCEDURE INFORMATION

Concomitant Procedures Performed ⁷⁰⁶⁵ : ☐ No ☐ Yes	
→If Yes, Procedure Type(s) ⁷⁰⁶⁶ : (select the best option(s)): _____	
Operator Name/NPI ^{14476, 14477, 14478, 14479} : _____, _____	
Procedure Status ⁷⁰²⁵ : ☐ Elective ☐ Urgent ☐ Emergency ☐ Salvage	
Procedure Location ¹²⁸⁷¹ : ☐ Cardiac CathLab ☐ Hybrid CathLab Suite ☐ Hybrid OR Suite ☐ Other	
Anesthesia Type ¹³³³¹ : ☐ General Anesthesia ☐ Deep sedation/Analgesia ☐ Moderate Sedation/Analgesia ☐ Minimal Sedation/Anxiolysis	
Procedure Aborted ¹³⁵⁰⁵ : ☐ No ☐ Yes	
→If Yes, Reason ¹³⁵⁰⁶ : ☐ Access Related ☐ Consent Issue ☐ Device Delivery System Malfunction ☐ Navigation Issue After Successful Access ☐ New Clinical Findings ☐ Patient Clinical Status ☐ System Issue ☐ Transseptal Access Related ☐ Other	
→If Yes, Action ¹³⁷⁵⁷ : ☐ Conversion to Open Heart Surgery ☐ Scheduled Open Heart Surgery ☐ Rescheduled Transcatheter Procedure ☐ Converted to Clinical Trial ☐ Balloon Valvuloplasty ☐ Converted to Medical Therapy ☐ Other	



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PROCEDURE INFORMATION (CONT.)

Conversion to Open Heart Surgery¹³⁵⁴²: ☐ No ☐ Yes

→If Yes, Reason¹³⁵⁴³: ☐ Access Related ☐ Cardiac Tamponade ☐ Inability to Position Device ☐ Device Embolization
☐ Valve Injury ☐ Other

Mechanical Support⁷⁴²²: ☐ No ☐ Yes **→If Yes, Device⁷⁴²³:** _____

→If Yes, Timing⁷⁴²⁴: ☐ In place at start of procedure ☐ Inserted during procedure and prior to intervention ☐ Inserted after intervention has begun ☐ Post Procedure

CardioPulmonary Bypass Used¹³⁵⁷⁹: ☐ No ☐ Yes

→If Yes, Status¹³⁵⁸⁰: ☐ Elective ☐ Emergency **→If Yes, CPB Time¹³⁵⁸¹:** _____ min

PROCEDURE MEDICATIONS (DURING THE PROCEDURE)

Positive Inotropes¹³⁶⁴⁴ ☐ No ☐ Yes

RADIATION AND CONTRAST

CODE ALL AVAILABLE MEASUREMENTS **Dose Area Product¹⁴²⁷⁸:** _____ ☐ Gy · cm² ☐ dGy · cm² ☐ cGy · cm² ☐ mGy · cm² ☐ μGy · M²
Cumulative Air Kerma⁷²¹⁰: _____ ☐ mGy ☐ Gy **Fluoro Time⁷²¹⁴:** _____ min **Contrast Volume⁷²¹⁵:** _____ mL

POST IMPLANT MITRAL VALVE DATA

MV Gradient (mean)¹³⁷⁶² (post implant): _____ mm Hg

Mitral Regurgitation¹⁴²⁷⁴ (post implant): ☐ None ☐ Trace/Trivial ☐ Mild ☐ Moderate ☐ Severe

TMVr PROCEDURE INFORMATION - INDICATIONS FOR MITRAL LEAFLET CLIP PROCEDURE

Mitral Leaflet Clip Procedure Indication (Check all that apply)¹³⁷⁹²:

- ☐ Refractory to Guideline Determined Optimal Medical Therapy
- ☐ Hostile Chest
- ☐ Severe Liver Disease (Cirrhosis or MELD score >12)
- ☐ Predicted STS MV Repair Operative Mortality Risk of >=6% (for patients deemed likely to undergo MV repair)
- ☐ Predicted STS MV Replacement Operative Mort Risk >=8% (for patients deemed likely to undergo MV replacement)
- ☐ Right Ventricular Dysfunction w/Severe Tricuspid Regurg
- ☐ AIDS
- ☐ Immobility
- ☐ High Risk of Aspiration
- ☐ Frailty
- ☐ Severe Pulmonary Hypertension
- ☐ Porcelain Aorta (or extensively calcified ascending aorta)
- ☐ Major Bleeding Diathesis
- ☐ Severe Dementia
- ☐ Chemotherapy for Malignancy
- ☐ IMA at High Risk of Injury
- ☐ Other

TMVr PROCEDURE INFORMATION

Guiding Cath Access Site¹³⁷⁹⁴: ☐ Right Femoral Vein ☐ Left Femoral Vein ☐ Jugular Vein ☐ Other Vein

Steerable Guide Cath Device ID¹³⁷⁹⁵: _____ **Steerable Guide Cath Serial Number¹³⁷⁹⁶:** _____

→If Procedure Aborted is No, TMVr DEVICES	DEVICE 1 ¹³⁵³³	DEVICE 2 ¹³⁵³³
Device ID¹³⁷⁹⁷:	Refer to Device List	Refer to Device List
Location¹³⁸⁰⁰:	☐ A1P1 ☐ A2P2 ☐ A3P3 ☐ Other	☐ A1P1 ☐ A2P2 ☐ A3P3 ☐ Other
Device Implanted Successfully¹³⁷⁹⁹:	☐ No ☐ Yes	☐ No ☐ Yes
→If Yes, Device Serial #¹³⁷⁹⁸:		
→If Yes, UDI¹⁴⁵⁷⁴:		
→If Yes, Deployed Then Removed¹³⁸⁰²:	☐ No ☐ Yes	☐ No ☐ Yes
→If No, Reason¹³⁸⁰¹:	☐ Adverse Event ☐ Device Malfunction ☐ Inability to Grasp Leaflets ☐ Inability to Reduce MR ☐ MV Injury ☐ Mitral Stenosis ☐ Other	☐ Adverse Event ☐ Device Malfunction ☐ Inability to Grasp Leaflets ☐ Inability to Reduce MR ☐ MV Injury ☐ Mitral Stenosis ☐ Other



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POST-PROCEDURE - INTRA OR POST-PROCEDURE EVENTS (COMPLETE FOR EACH PROCEDURE TYPE AND EVERY OCCURRENCE)

INTRA OR POST PROCEDURE EVENT(S) ¹²¹⁵³	EVENT(S) OCCURRED ⁹⁰⁰²	→ IF YES, EVENT DATE(S) ¹⁴²⁷⁵
ASD Defect Closure due to Transseptal Catheterization	☐ No ☐ Yes	mm / dd / yyyy
Atrial Fibrillation	☐ No ☐ Yes	mm / dd / yyyy
Bleeding – Access Site	☐ No ☐ Yes	mm / dd / yyyy
Bleeding – Gastrointestinal	☐ No ☐ Yes	mm / dd / yyyy
Bleeding – Genitourinary	☐ No ☐ Yes	mm / dd / yyyy
Bleeding – Other	☐ No ☐ Yes	mm / dd / yyyy
Bleeding - Hematoma at Access Site	☐ No ☐ Yes	mm / dd / yyyy
Bleeding – Retroperitoneal	☐ No ☐ Yes	mm / dd / yyyy
Cardiac Arrest	☐ No ☐ Yes	mm / dd / yyyy
Cardiac Perforation	☐ No ☐ Yes	mm / dd / yyyy
Cardiac Surgery or Intervention – Other Unplanned	☐ No ☐ Yes	mm / dd / yyyy
Complete Leaflet Clip Detachment	☐ No ☐ Yes	mm / dd / yyyy
Delivery System Component Embolization	☐ No ☐ Yes	mm / dd / yyyy
COVID19	☐ No ☐ Yes	mm / dd / yyyy
Device Embolization	☐ No ☐ Yes	mm / dd / yyyy
Device Thrombosis	☐ No ☐ Yes	mm / dd / yyyy
Device Related Event – Other	☐ No ☐ Yes	mm / dd / yyyy
Dialysis (New Requirement)	☐ No ☐ Yes	mm / dd / yyyy
Endocarditis	☐ No ☐ Yes	mm / dd / yyyy
Mitral Leaflet or Subvalvular Injury	☐ No ☐ Yes	mm / dd / yyyy
Myocardial Infarction	☐ No ☐ Yes	mm / dd / yyyy
Permanent Pacemaker	☐ No ☐ Yes	mm / dd / yyyy
Reintervention – Mitral Valve (complete event info)	☐ No ☐ Yes	mm / dd / yyyy
Single Leaflet Device Attachment	☐ No ☐ Yes	mm / dd / yyyy
Stroke – Ischemic (complete event info)	☐ No ☐ Yes	mm / dd / yyyy
Stroke – Hemorrhagic (complete event info)	☐ No ☐ Yes	mm / dd / yyyy
Stroke – Undetermined (complete event info)	☐ No ☐ Yes	mm / dd / yyyy
Transient Ischemic Attack (TIA) (complete event info)	☐ No ☐ Yes	mm / dd / yyyy
Transseptal Complication	☐ No ☐ Yes	mm / dd / yyyy
Vascular Complication – Major	☐ No ☐ Yes	mm / dd / yyyy
Vascular Complication – Minor	☐ No ☐ Yes	mm / dd / yyyy
Vascular Surgery or Intervention – Unplanned	☐ No ☐ Yes	mm / dd / yyyy



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IN-HOSPITAL EVENT INFORMATION (COMPLETE FOR EACH ISCHEMIC, HEMORRHAGIC, UNDETERMINED STROKE, TIA OR MV RE-INTERVENTION)

Event¹⁴³¹²:

Event Date¹⁴³¹³:

mm / dd / yyyy

☐ Ischemic Stroke(In-hospital) ☐ Hemorrhagic Stroke(In-hospital) ☐ Undetermined Stroke(In-hospital) ☐ TIA(In-hospital)
☐ Mitral Valve Re-intervention(In-hospital)

Status¹⁴³¹⁴:

☐ Alive

☐ Deceased

→If Deceased, Date of Death:¹⁴³¹⁵ mm / dd / yyyy

Clinical Comments¹⁴⁴⁶²:

→If EVENT¹⁴³¹² = STROKE OR TIA (IN-HOSPITAL)

Symptom Onset Date¹⁴³¹⁶: mm / dd / yyyy

Neurologic Deficit with Rapid Onset¹⁴³¹⁷:

☐ No ☐ Yes

→If Yes, Clinical Presentation¹⁴³¹⁸:

☐ Stroke/TIA ☐ Non-Stroke

→If Stroke/TIA, Symptom Duration ≥ 24 hours¹⁴³¹⁹:

☐ No ☐ Yes

→If Stroke/TIA, Brain Imaging Performed¹⁴³²⁰:

☐ No ☐ Yes

→If Yes, Brain Imaging Type¹⁴³⁴⁹:

☐ CT ☐ CT w/Contrast ☐ MRI ☐ MRI w/Contrast ☐ Other (e.g. angiography)

→If Yes, Brain Imaging Findings¹⁴³⁵⁰:

☐ Infarct ☐ Hemorrhage ☐ No Deficit

→If Stroke/TIA, Event Related Sequelae¹⁴³⁵¹ (Select all that apply):

☐ Death ☐ Permanent Vegetative State

☐ Altered Consciousness ☐ Blindness ☐ Aphasia ☐ Loss of Motor Function

☐ Loss of Sensory Function ☐ Facial Paralysis ☐ Prolonged Length of Stay ☐ Other

→If Status=Alive, Discharge Location¹⁴³⁵²:

☐ Home ☐ Skilled Nursing Facility ☐ Extended Care/TCU/Rehab ☐ Other Discharge Location

→If Status=Alive, Patient Discharged to Prior Place of Living¹⁴⁴²¹:

☐ No ☐ Yes

→If Status=Deceased, Stroke Diagnosed During Autopsy¹⁴³⁵³:

☐ No ☐ Yes ☐ Info Not Available

→If EVENT¹⁴³¹² = MITRAL VALVE RE-INTERVENTION (IN-HOSPITAL)

Mitral Valve Re-intervention Type¹⁴³⁶⁰:

☐ Surgical Replacement ☐ Surgical Repair ☐ Transcatheter Replacement
☐ Balloon Valvuloplasty ☐ Leaflet Clip Procedure ☐ Paravalvular Leak Closure
☐ Other Transcatheter Intervention

MV Re-intervention Indication¹⁴³⁶¹:

☐ Regurgitation ☐ Stenosis ☐ Device Embolization
☐ Endocarditis ☐ Device Thrombosis ☐ Valve Injury ☐ Other



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POST-PROCEDURE LABS AND ECG (COMPLETE FOR EACH PROCEDURE TYPE)

Hemoglobin (lowest)¹³⁷⁶³: _____ (g/dL) ☐ Not Drawn¹⁴²⁴³ **Creatinine (highest)**¹³⁷⁶⁴: _____ (mg/dL) ☐ Not Drawn¹⁴²⁹³

12-Lead ECG Performed¹³⁶¹⁶: ☐ No ☐ Yes

→ If Yes, **12-Lead ECG Findings**¹³⁷⁶⁵ (Check all that apply): ☐ No Significant Changes ☐ Pathological Q Wave ☐ New LBBB ☐ Cardiac Arrhythmia

POST-PROCEDURE ECHOCARDIOGRAM (COMPLETE FOR EACH PROCEDURE)

Echocardiogram¹³⁵⁹²: ☐ Yes – TTE ☐ Yes - TEE ☐ Not Performed¹³⁶⁴⁵ → If Yes, **Date**¹³⁴⁹³: mm / dd / yyyy

→ If Yes, **Mitral Regurgitation (highest)**¹³⁴⁹⁴: ☐ None ☐ Trace/Trivial ☐ Mild ☐ Moderate ☐ Moderate-Severe ☐ Severe

→ If Yes, **Effective Regurgitant Orifice Area (EROA)**¹³⁷⁷⁹: _____ cm² → If EROA, **Method of Assessment**¹³⁷⁶⁹: ☐ 3D Planimetry ☐ PISA ☐ Quantitative Dopplar ☐ Other

→ If Yes, **MV Mean Gradient**¹³⁷⁷⁰: (highest) _____ mm Hg

E. DISCHARGE

Discharge Date¹⁰¹⁰⁰: mm / dd / yyyy

Discharge Provider Name, NPI^{10070,10072,10071,10073}: _____ Last Name, First Name, MI, NPI

Discharge Status¹⁰¹⁰⁵ ☐ Alive ☐ Deceased

→ If Alive, **Cardiac Rehabilitation Referral**¹⁰¹¹⁶: ☐ No - Reason Not Documented ☐ No - Medical Reason Documented ☐ No - Health Care System Reason Documented ☐ No - Patient-Oriented Reason ☐ Yes

→ If Alive, **Discharge Location**¹⁰¹¹⁰: ☐ Home ☐ Skilled Nursing Facility ☐ Extended Care/TCU/Rehab ☐ Other Acute Care Hospital ☐ Left Against Medical Advice (AMA) ☐ Other Discharge Location

→ If Alive, **Hospice Care**¹⁰¹¹⁵: ☐ No ☐ Yes

→ If Deceased, **Death During Procedure**¹⁰¹²⁰: ☐ No ☐ Yes

→ If Deceased, **Cause of Death**¹⁰¹²⁵:

- | | | |
|---|--|---|
| ☐ Acute myocardial infarction | ☐ Pulmonary | ☐ Hemorrhage |
| ☐ Sudden cardiac death | ☐ Renal | ☐ Non-cardiovascular procedure or surgery |
| ☐ Heart failure | ☐ Gastrointestinal | ☐ Trauma |
| ☐ Stroke | ☐ Hepatobiliary | ☐ Suicide |
| ☐ Cardiovascular procedure | ☐ Pancreatic | ☐ Neurological |
| ☐ Cardiovascular hemorrhage | ☐ Infection | ☐ Malignancy |
| ☐ Other cardiovascular reason | ☐ Inflammatory/Immunologic | ☐ Other non-cardiovascular reason |

PRBCs Transfused⁹²⁷⁵: ☐ No ☐ Yes Note: Code the total # of units between start of the procedure and discharge

→ If Yes, **PRBCs Units Transfused**¹³⁶⁷⁰: _____

DISCHARGE MEDICATIONS D/c meds are not required for patients who expired, discharged to "Other Acute Care Hospital," "AMA", or are receiving Hospice Care.

CATEGORY	MEDICATION CODE ¹⁰²⁰⁰	PRESCRIBED ¹⁰²⁰⁵				→ If Yes, LOOP DIURETIC DOSE ¹⁴⁵⁷⁶
		YES	NO- NO REASON	NO- MEDICAL REASON	NO- PT REASON	
ACE Inhibitors (Angiotensin Converting Enzyme)	Angiotensin Converting Enzyme Inhibitor	☐	☐	☐	☐	
Aldosterone Antagonist	Aldosterone Antagonist	☐	☐	☐	☐	
Anticoagulant	Direct Thrombin Inhibitor	☐	☐	☐	☐	
	Warfarin	☐	☐	☐	☐	
Antiplatelet	Aspirin	☐	☐	☐	☐	
ARB (Angiotensin Receptors Blockers)	Angiotensin II Receptor Blocker	☐	☐	☐	☐	
Beta Blockers	Beta Blocker	☐	☐	☐	☐	
	Diuretics Not Otherwise Specified	☐	☐	☐	☐	
	Loop Diuretics	☐	☐	☐	☐	_____ mg
Diuretics	Thiazides	☐	☐	☐	☐	
		☐	☐	☐	☐	
Non-Vitamin K Dependent Oral Anticoagulant	Direct Factor Xa Inhibitor	☐	☐	☐	☐	
P2Y12 Inhibitors	P2Y12 Antagonist	☐	☐	☐	☐	



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F. FOLLOW-UP Follow-up should be performed at the following intervals post-procedure: **30 days (- 7 days/+ 75), 1 year (+/- 60 days)**

Follow-up Assessment Date ¹¹⁰⁰⁰ :	mm / dd / yyyy																					
Reference Episode Arrival Date/Time ¹¹⁰⁰² :	mm / dd / yyyy HH:MM																					
Reference Episode Discharge Date ¹⁴³³⁸ :	mm / dd / yyyy																					
Reference Procedure Start Date/Time ¹¹⁰⁰¹ :	mm / dd / yyyy HH:MM																					
Reference Procedure Type ¹³⁷⁰⁵ :	☐ TAVR ☐ TMVr ☐ TMVR ☐ Tricuspid Valve Procedure																					
Method(s) to Determine Status ¹¹⁰⁰³ :	☐ Office Visit ☐ Medical Records ☐ Letter from Medical Provider ☐ Phone Call ☐ Social Security Death Master File ☐ Hospitalized ☐ Obituary List ☐ CMS Linked Data ☐ Other																					
Follow-up Status ¹¹⁰⁰⁴ :	☐ Alive ☐ Deceased ☐ Lost to Follow-up																					
→ If Alive, Residence ¹³⁸⁰⁵ :	☐ Home with No Health Aid ☐ Home with Health Aid ☐ Long Term Care ☐ Other ☐ Not Documented ¹⁴⁵¹¹																					
→ If Deceased, Date of Death ¹¹⁰⁰⁶ :	mm / dd / yyyy																					
→ If Deceased, Cause of Death ¹¹⁰⁰⁷ :	<table><tr><td>☐ Acute myocardial infarction</td><td>☐ Pulmonary</td><td>☐ Hemorrhage</td></tr><tr><td>☐ Sudden cardiac death</td><td>☐ Renal</td><td>☐ Non-cardiovascular procedure or surgery</td></tr><tr><td>☐ Heart failure</td><td>☐ Gastrointestinal</td><td>☐ Trauma</td></tr><tr><td>☐ Stroke</td><td>☐ Hepatobiliary</td><td>☐ Suicide</td></tr><tr><td>☐ Cardiovascular procedure</td><td>☐ Pancreatic</td><td>☐ Neurological</td></tr><tr><td>☐ Cardiovascular hemorrhage</td><td>☐ Infection</td><td>☐ Malignancy</td></tr><tr><td>☐ Other cardiovascular reason</td><td>☐ Inflammatory/Immunologic</td><td>☐ Other non-cardiovascular reason</td></tr></table>	☐ Acute myocardial infarction	☐ Pulmonary	☐ Hemorrhage	☐ Sudden cardiac death	☐ Renal	☐ Non-cardiovascular procedure or surgery	☐ Heart failure	☐ Gastrointestinal	☐ Trauma	☐ Stroke	☐ Hepatobiliary	☐ Suicide	☐ Cardiovascular procedure	☐ Pancreatic	☐ Neurological	☐ Cardiovascular hemorrhage	☐ Infection	☐ Malignancy	☐ Other cardiovascular reason	☐ Inflammatory/Immunologic	☐ Other non-cardiovascular reason
☐ Acute myocardial infarction	☐ Pulmonary	☐ Hemorrhage																				
☐ Sudden cardiac death	☐ Renal	☐ Non-cardiovascular procedure or surgery																				
☐ Heart failure	☐ Gastrointestinal	☐ Trauma																				
☐ Stroke	☐ Hepatobiliary	☐ Suicide																				
☐ Cardiovascular procedure	☐ Pancreatic	☐ Neurological																				
☐ Cardiovascular hemorrhage	☐ Infection	☐ Malignancy																				
☐ Other cardiovascular reason	☐ Inflammatory/Immunologic	☐ Other non-cardiovascular reason																				

FOLLOW-UP CLINICAL ASSESSMENT

Hemoglobin ¹³⁷⁷⁵ :	g/dL	☐ Not Drawn ¹⁴³²⁶	Creatinine ¹³³¹⁰ :	mg/dL	☐ Not Drawn ¹³³¹¹
NYHA Classification ¹³⁶⁸⁸ :	☐ I ☐ II ☐ III ☐ IV ☐ Not Documented ¹⁴³³³				
12-Lead ECG Performed ¹³⁶⁸⁹ :	☐ No ☐ Yes				
→ If Yes, 12-Lead ECG Findings ¹³⁶²¹	(Check all that apply): ☐ No Significant Changes ☐ Pathological Q Wave ☐ New LBBB ☐ Cardiac Arrhythmia				

FOLLOW-UP IMAGING – ECHOCARDIOGRAM

Echocardiogram ¹³⁴⁹² :	☐ Yes - TTE ☐ Yes - TEE ☐ Not Performed ¹⁴⁵¹²	→ If Yes, Date ¹³⁵⁹³ :	mm / dd / yyyy	
→ If Yes, LVEF ¹³⁶⁹⁰ :	%	☐ LVEF Not Assessed ¹³⁶⁹¹		
→ If Yes, Mitral Regurgitation ¹³⁶⁷³ :	☐ None ☐ Trace/Trivial ☐ Mild ☐ Moderate ☐ Moderate-Severe ☐ Severe			
→ If Yes, MV Mean Gradient ¹³⁷⁷⁸ : (highest)	mm Hg			
→ If Yes, Effective Regurgitant Orifice Area (EROA) ¹³⁷⁶⁸ :	cm ²		→ If EROA, Method of Assessment ¹³⁷⁸⁰ :	☐ 3D Planimetry ☐ PISA ☐ Quantitative Doppler ☐ Other
→ If Yes, Left Ventricular Internal Systolic Dimension ¹³⁷⁸³ :	cm		☐ Not Measured ¹⁴⁵³⁶	
→ If Yes, Left Ventricular Internal Diastolic Dimension ¹³⁷⁸⁴ :	cm		☐ Not Measured ¹⁴⁵³⁷	
→ If Yes, Left Ventricular End Systolic Volume ¹³⁷⁸⁶ :	mL		☐ Not Measured ¹⁴⁵³⁹	
→ If Yes, Left Ventricular End Diastolic Volume ¹³⁷⁸⁵ :	mL		☐ Not Measured ¹⁴⁵³⁸	
→ If Yes, Left Atrial Volume ¹³⁷⁸⁷ :	mL ☐ Not Measured ¹⁴⁵⁴⁰		(OR) LA Volume Index ¹³⁷⁸⁸ :	mL/m ² ☐ Not Measured ¹⁴⁵⁸²

FOLLOW-UP SIX MINUTE WALK TEST AND KCCQ

Six Minute Walk Test ¹³⁷⁸⁹ :	☐ No ☐ Yes				
→ If Yes, Test Date ¹³⁷⁹⁰ :	mm / dd / yyyy		→ If Yes, Total Distance ¹⁴³²⁵ :	ft	
→ If No, Reason ¹⁴²⁶³ :	☐ Non-Cardiac Reason ☐ Cardiac Reason ☐ Patient Not Willing to Walk ☐ Not Performed by Site				
KCCQ-12 Performed ¹³⁸⁴⁵ :	☐ No ☐ Yes		→ If Yes, KCCQ-12 Date ¹³⁸⁴⁴ :	mm / dd / yyyy	
→ If Yes, KCCQ-12 ^{13847, 69, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68} :	(see separate questionnaire)		Q1a:	Q1b:	Q1c:
Q5:	Q6:	Q7:	Q8a:	Q8b:	Q8c:
KCCQ Summary Score ¹⁴⁵³⁵ : (calculated)					



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FOLLOW-UP MEDICATIONS						
CATEGORY	MEDICATION CODE ¹¹⁹⁹⁰	PRESCRIBED ¹³⁶⁹⁶				→ If Yes, LOOP DIURETIC DOSE ¹⁴⁵⁷⁷
		YES	NO- NO REASON	NO- MEDICAL REASON	NO- PT REASON	
ACE Inhibitors (Angiotensin Converting Enzyme)	Angiotensin Converting Enzyme Inhibitor	☐	☐	☐	☐	
Aldosterone Antagonist	Aldosterone Antagonist	☐	☐	☐	☐	
Anticoagulant	Direct Thrombin Inhibitor	☐	☐	☐	☐	
	Warfarin	☐	☐	☐	☐	
Antiplatelet	Aspirin	☐	☐	☐	☐	
ARB (Angiotensin Receptors Blockers)	Angiotensin II Receptor Blocker	☐	☐	☐	☐	
Beta Blockers	Beta Blocker	☐	☐	☐	☐	
Diuretics	Diuretics Not Otherwise Specified	☐	☐	☐	☐	
	Loop Diuretics	☐	☐	☐	☐	_____ mg
	Thiazides	☐	☐	☐	☐	
Non-Vitamin K Dependent Oral Anticoagulant	Direct Factor Xa Inhibitor	☐	☐	☐	☐	
P2Y12 Inhibitor	P2Y12 Antagonist	☐	☐	☐	☐	
FOLLOW-UP EVENTS SPECIFY THE EVENTS (AND EVENT DATES) THAT OCCURRED BETWEEN DISCHARGE AND 30 DAY (FIRST) FOLLOW-UP (FU), OR BETWEEN FU ASSESSMENT DATE #1 AND #2.						
EVENT(s) ¹²⁹³³	EVENT(s) OCCURRED ¹⁴²⁷⁶		→ IF YES, EVENT DATE(s) ¹⁴²⁷⁷			
ASD Defect Closure due to Transseptal Catheterization	☐ No	☐ Yes	mm / dd / yyyy			
Atrial Fibrillation	☐ No	☐ Yes	mm / dd / yyyy			
Bleeding – Life Threatening	☐ No	☐ Yes	mm / dd / yyyy			
Bleeding – Major	☐ No	☐ Yes	mm / dd / yyyy			
Cardiac Surgery or Intervention – Other Unplanned	☐ No	☐ Yes	mm / dd / yyyy			
COVID19	☐ No	☐ Yes	mm / dd / yyyy			
Device Embolization	☐ No	☐ Yes	mm / dd / yyyy			
Device Thrombosis	☐ No	☐ Yes	mm / dd / yyyy			
Device Related Event – Other	☐ No	☐ Yes	mm / dd / yyyy			
Dialysis (New Requirement)	☐ No	☐ Yes	mm / dd / yyyy			
Endocarditis	☐ No	☐ Yes	mm / dd / yyyy			
Myocardial Infarction	☐ No	☐ Yes	mm / dd / yyyy			
Permanent Pacemaker	☐ No	☐ Yes	mm / dd / yyyy			
Readmission – Cardiac (Not Heart Failure)	☐ No	☐ Yes	mm / dd / yyyy			
Readmission – Heart Failure (Complete event info)	☐ No	☐ Yes	mm / dd / yyyy			
Readmission – Non-Cardiac	☐ No	☐ Yes	mm / dd / yyyy			
Reintervention – Mitral Valve (Complete event info)	☐ No	☐ Yes	mm / dd / yyyy			
Single Leaflet Device Attachment	☐ No	☐ Yes	mm / dd / yyyy			
Stroke – Ischemic (complete event info)	☐ No	☐ Yes	mm / dd / yyyy			
Stroke – Hemorrhagic (complete event info)	☐ No	☐ Yes	mm / dd / yyyy			
Stroke – Undetermined (complete event info)	☐ No	☐ Yes	mm / dd / yyyy			
Transient Ischemic Attack (TIA) (complete event info)	☐ No	☐ Yes	mm / dd / yyyy			
Vascular Complication – Major	☐ No	☐ Yes	mm / dd / yyyy			
Vascular Complication – Minor	☐ No	☐ Yes	mm / dd / yyyy			
Vascular Surgery or Intervention – Unplanned	☐ No	☐ Yes	mm / dd / yyyy			



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FOLLOW-UP EVENT INFORMATION (COMPLETE FOR EACH ISCHEMIC, HEMORRHAGIC, UNDETERMINED STROKE, TIA, MV RE-INTERVENTION OR HF READMISSION)

Event¹⁴³⁸⁵:

Event Date¹⁴³⁸⁶:

mm / dd / yyyy

☐ Ischemic Stroke (follow-up) ☐ Hemorrhagic Stroke (follow-up) ☐ Undetermined Stroke (follow-up) ☐ TIA (follow-up)
☐ Mitral Valve Re-intervention (follow-up) ☐ Heart Failure Readmission (follow-up)

Status¹⁴³⁸⁷:

☐ Alive

☐ Deceased

→If Deceased, Date of Death¹⁴³⁸⁸:

mm / dd / yyyy

Clinical Comments¹⁴⁴⁶³:

→If EVENT¹⁴³⁸⁵ = STROKE OR TIA (FOLLOW-UP)

Symptom Onset Date¹⁴³⁸⁹:

mm / dd / yyyy

Neurologic Deficit with Rapid Onset¹⁴³⁹⁰:

☐ No ☐ Yes

→If Yes, Clinical Presentation¹⁴³⁹¹:

☐ Stroke/TIA ☐ Non-Stroke

→If Stroke/TIA, Symptom Duration ≥ 24 hours¹⁴³⁹²:

☐ No ☐ Yes

→If Stroke/TIA, Brain Imaging Performed¹⁴³⁹³:

☐ No ☐ Yes

→If Yes, Brain Imaging Type¹⁴³⁹⁴:

☐ CT ☐ CT w/Contrast ☐ MRI ☐ MRI w/Contrast ☐ Other (e.g. angiography)

→If Yes, Brain Imaging Findings¹⁴³⁹⁵:

☐ Infarct ☐ Hemorrhage ☐ No Deficit

→If Stroke/TIA, Event Related Sequelae¹⁴³⁹⁶ (Select all that apply):

☐ Death ☐ Permanent Vegetative State

☐ Altered Consciousness

☐ Blindness

☐ Aphasia

☐ Loss of Motor Function

☐ Loss of Sensory Function

☐ Facial Paralysis

☐ Prolonged Length of Stay

☐ Other

→If Status=Alive, Discharge Location¹⁴⁴²⁰:

☐ Home ☐ Skilled Nursing Facility ☐ Extended Care/TCU/Rehab ☐ Other Discharge Location

→If Status=Alive, Patient Discharged to Prior Place of Living¹⁴⁴²²:

☐ No ☐ Yes

→If Status=Deceased, Stroke Diagnosed During Autopsy¹⁴³⁹⁷:

☐ No ☐ Yes ☐ Info Not Available

→If EVENT¹⁴³⁸⁵ = MITRAL VALVE RE-INTERVENTION (FOLLOW-UP)

Mitral Valve Re-intervention Type¹⁴⁴⁰⁵:

☐ Surgical Replacement ☐ Surgical Repair ☐ Transcatheter Replacement
☐ Balloon Valvuloplasty ☐ Leaflet Clip Procedure ☐ Paravalvular Leak Closure
☐ Other Transcatheter Intervention

MV Re-intervention Indication¹⁴⁴⁰⁶:

☐ Regurgitation ☐ Stenosis ☐ Device Embolization
☐ Endocarditis ☐ Device Thrombosis ☐ Valve Injury ☐ Other

→If EVENT¹⁴³⁸⁵ = READMISSION (HEART FAILURE)

Hospitalization ≥24 Hours¹⁴³⁸⁰:

☐ No ☐ Yes ☐ Information Not Available

Clinical Signs and/or Symptoms of Heart Failure¹⁴³⁸¹:

☐ No ☐ Yes ☐ Information Not Available

IV or Invasive Treatment Required¹⁴³⁸²:

☐ No ☐ Yes ☐ Information Not Available

Note: IV includes diuretics or vasoactive therapy; invasive treatment includes ultrafiltration, IABP or mechanical assistance.