Transcatheter Mitral Valve Repair & Replacement

2026 Physician and Facility Billing Guide

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Edwards

Edwards PASCAL Precision Transcatheter Valve Repair System

The PASCAL Precision transcatheter valve repair system (the PASCAL Precision system) is indicated for the percutaneous reduction of significant, symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the MR.

Edwards SAPIEN M3 Transcatheter Mitral Valve Replacement System

The SAPIEN M3 transcatheter mitral valve replacement system (SAPIEN M3 system) is indicated for the treatment of symptomatic moderate-to-severe or severe mitral regurgitation (MR) in patients who are deemed unsuitable for surgery or transcatheter edge-to-edge repair (M-TEER) therapy by a multidisciplinary heart team. The SAPIEN M3 system is also indicated for the treatment of symptomatic mitral valve dysfunction (moderate-to-severe or severe MR, severe mitral stenosis (MS), or moderate MR with moderate MS) associated with mitral annular calcification (MAC) in patients who are deemed unsuitable for surgery or M-TEER therapy by a multidisciplinary heart team. The Edwards 23F guide sheath is indicated to provide venous vascular access to cardiac structures enabling the introduction and removal of SAPIEN M3 transcatheter mitral valve replacement devices.

Abbreviations

Mitral Valve Transcatheter Edge-to-Edge Repair (M-TEER): A catheter-based repair technique in which the mitral leaflets are approximated at their edges to reduce regurgitation.

Transcatheter Mitral Valve Replacement (TMVR): The percutaneous replacement of the mitral valve using a catheter-delivered prosthesis, encompassing valve-in-valve, valve-in-ring, valve-in-MAC, and valve-in-native procedures.

Transcatheter Mitral Valve Implantation (TMVI): A subset of TMVR referring specifically to the percutaneous implantation of a catheter-delivered prosthetic valve into the native mitral annulus without prior prosthetic valve or annuloplasty ring.

Physician Services

Physicians use Current Procedural Terminology (CPT) codes to bill for procedures and services. Category I CPT codes are assigned unique relative value units (RVUs), which are used to determine payment by the Centers for Medicare and Medicaid Services (CMS).

Category I CPT codes have been implemented for mitral valve transcatheter edge-to-edge repair (M-TEER) procedures for mitral regurgitation. A Category III CPT code was created to describe transcatheter mitral valve replacement/implantation (TMVR/TMVI). In most cases, Category III CPT codes do not have assigned RVUs; therefore, no national payment rate is established, and payment is based on carrier discretion.

The following table details CPT coding options for services associated with repair with the PASCAL Precision system and implantation of the SAPIEN M3 valve.

CPT Codes[1,2]

CPT Code	Description	CY2026 Medicare National Physician Payment[3]	CY2026 Facility RVUs[3]
PASCAL Precision system (M-TEER)			
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis	$1,589	47.35
+33419	Additional prosthesis(es) during same session (List separately in addition to code for primary procedure)*	$370	11.02
SAPIEN M3 system (TMVR/TMVI)			
0483T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed	Based on carrier discretion	RVUs are not assigned
Transesophageal Echocardiography (TEE)			
93355	Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg,TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D	$193	5.75

CY 2026 payment rates effective January 1 - December 31, 2026. Beginning January 1, 2026, Medicare will determine payment based on two separate conversion factors, depending on whether the physician participates in an Advanced Alternative Payment Model (APM). All provider rates were calculated using the Qualifying Physician Conversion factor on January 1, 2026: $33.5675.

* Report a maximum number of one unit for add-on code 33419 if two or more devices are inserted. (+) indicates add-on code. List add-on code separately in addition to code for primary procedure.

Coding Modifiers [1,2]

For Medicare claims, see physician billing notes sections for additional information as all modifiers listed are not applicable to all codes. For non-Medicare claims, payer policy should be referenced for reporting instructions and appropriate use of modifiers.

Modifier	Description	Details
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study	Use with 33418, +33419 to identify M-TEER cases enrolled in the TVT registry.
59	Distinct Procedural Service	Use with diagnostic cardiac catheterization code(s) to identify qualified circumstances when diagnostic cardiac catheterization occurs on the same session/same day as the transcatheter valve procedure.
62*	Two Surgeons/Co-surgeons	Used to identify two surgeons working together as primary surgeons performing distinct part(s) of a procedure. Supporting documentation may be required to establish medical necessity.
66*	Surgical Team	Used to identify a surgical team.
80*	Assistant Surgeon	Used for physician claims where surgical assistant services are provided by a physician.
81*	Minimum Assistant Surgeon	
82*	Assistant Surgeon (when a qualified resident surgeon is not available)	
AS*	Physician assistant, nurse practitioner, or clinical nurse specialist services for assistant at surgery	Used for physician claims where surgical assistant services are provided by a physician assistant(PA), nurse practitioner(NP), or clinical nurse specialist (CNS).

* Supporting documentation may need to be submitted with the claim to establish medical necessity, see physician billing notes sections.

PASCAL Precision system (M-TEER) notes for physician billing

Procedure coding notes
Medicare will only pay M-TEER physician claims for CPT codes 33418 – 33419 when billed with the following: [4]

- Place of service (POS) code 21 (inpatient hospital)
- Modifier -Q0 (zero) signifying CED participation (qualifying registry or qualified clinical study)
- ICD-10-CM diagnosis codes I34.0 or I34.1 and secondary diagnosis code Z00.6 (encounter for examination for normal comparison and control in clinical research program)
- National Clinical Trial (NCT) number (e.g. the NCT number for the TVT Registry Mitral Module is 02245763). The 8-digit NCT number preceded by the two alpha characters "CT" is placed in Field 19 of paper Form CMS-1500 and entered WITHOUT the "CT" prefix in the electronic 837P in Loop 2300 REF02 (REF01=P4)

Medicare will return all other claims as not processable.

Procedure coding notes

The following services are INCLUDED in M-TEER (33418/+33419):

- The work, when performed, of percutaneous access, placing the access sheath, transseptal puncture, advancing the repair device delivery system into position, repositioning the device as needed, and deploying the device(s).
- Angiography, radiological supervision and interpretation performed to guide M-TEER (eg, guiding device placement and documenting completion of the intervention).

Additional M-TEER (33418, +33419) coding notes:

- Transesophageal echocardiology (93355) performed by a separate operator for guidance of the procedure may be separately reported. 93355 is reported once per intervention and only by an individual who is not performing the interventional procedure.
- When transcatheter ventricular support is required in conjunction with M-TEER, the appropriate code may be reported with the appropriate ventricular assist device (VAD) procedure code (33990, 33991, 33992, 33993, 33995, 33997) or balloon pump insertion code (33967, 33970, 33973).
- When cardiopulmonary bypass is performed in conjunction with M-TEER, 33418, +33419 may be reported with the appropriate add-on code for percutaneous peripheral bypass (33367), open peripheral bypass (33368), or central bypass (33369).
- Intracardiac echocardiography (+93662) may be separately reported, although many payers treat ICE as not separately reportable for structural heart interventions. Check current NCCI PTP edits and payer policy before billing.
- See page 7 for guidance on appropriate reporting of diagnostic right and left heart catheterization and diagnostic coronary angiography procedures with M-TEER.
- CPT code 33418 has a 90-day global period.

Additional M-TEER (33418, +33419) modifiers:

Co-surgeons (Modifier 62)

M-TEER may be a two-physician (interventional cardiologist and cardiac surgeon) procedure. **Medicare requires supporting documentation to prove medical necessity of two surgeons for the procedure.** When M-TEER is performed as a joint IC and CS procedure, each co-surgeon reports the same procedure code with the -62 modifier, and if medical necessity is proven, Medicare payment for each physician is 62.5% of the established payment.

Assistant at Surgery (Modifiers AS, 80, 81, and 82)

Documentation to prove medical necessity of an assistant at surgery is not required. Modifier AS is used when assistant at surgery services are provided by a physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS). Modifiers 80, 81 and 82 are for Physician use only.

Team Surgeons (Modifier 66)

A surgical team approach is not permissible for M-TEER. Modifier 66 may not be billed with 33418 or +33419.

SAPIEN M3 system (TMVR/TMVI) notes for physician billing

Procedure coding notes

The following services are INCLUDED in TMVR/TMVI (0483T):

- Vascular access, catheterization, balloon valvuloplasty, deploying the valve, repositioning the valve as needed, temporary pacemaker insertion for rapid pacing, and access site closure, when performed.
- Angiography, radiological supervision and interpretation, intraprocedural roadmapping (eg, contrast injections, fluoroscopy) to guide the TMVR/TMVI, left ventriculography (eg, to assess mitral regurgitation for guidance of TMVR/TMVI), and completion angiography.

Additional TMVR/TMVI (0483T) coding notes:

- Transesophageal echocardiology (93355) performed by a separate operator for guidance of the procedure may be separately reported. 93355 is reported once per intervention and only by an individual who is not performing the interventional procedure.
- When cardiopulmonary bypass is performed in conjunction with TMVR/TMVI, the procedure may be separately reported with the appropriate add-on code for percutaneous peripheral bypass (33367), open peripheral bypass (33368), or central bypass (33369).
- Intracardiac echocardiography (+93662) may be separately reported, although many payers treat ICE as not separately reportable for structural heart interventions. Check current NCCI PTP edits and payer policy before billing.
- See page 7 for guidance on appropriate reporting of diagnostic right and left heart catheterization and diagnostic coronary angiography procedures with TMVR/TMVI.
- CPT code 0483T has a 0-day global period.

Additional TMVR/TMVI (0483T) modifiers:

Co-Surgeons (Modifier 62)
TMVR/TMVI may be a two-physician (interventional cardiologist and cardiac surgeon) procedure. Medicare does not require documentation to prove medical necessity if the two- specialty requirement is met. When TMVR/TMVI is performed as a joint IC and CS procedure, each co-surgeon reports the same procedure code with the -62 modifier, and Medicare payment for each physician is 62.5% of the established payment.

Assistant at Surgery (Modifiers AS, 80, 81, and 82)
Documentation to prove medical necessity of an assistant at surgery is not required. Modifier AS is used when assistant at surgery services are provided by a physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS). Modifiers 80, 81 and 82 are for Physician use only.

Team Surgeons (Modifier 66)
Medicare requires supporting documentation to prove medical necessity of a team.

Diagnostic right and left heart catheterization and diagnostic coronary angiography guidelines for physician billing

Coding guidelines for diagnostic right and left heart catheterization and angiography with M-TEER and TMVR/TMVI

Diagnostic right and left heart catheterization codes (93451, 93452, 93453, 93456, 93457, 93458, 93459, 93460, 93461, 93593, 93594, 93595, 93596, 93597, 93598) should not be used with M-TEER (33418, +33419) or TMVR/TMVI (0483T) to report:

1. Contrast injections, angiography, road-mapping, and/ or fluoroscopic guidance for the transcatheter mitral valve repair (M-TEER) or the transcatheter mitral valve replacement/implantation (TMVR/TMVI),
2. Left ventricular angiography to assess mitral regurgitation for guidance of M-TEER, or
3. Left ventricular angiography to assess or confirm valve positioning and function in TMVR/TMVI, or
4. Right and left heart catheterization for hemodynamic measurements before, during, and after the procedure for guidance of the procedure.

Diagnostic right and left heart catheterization codes (93451, 93452, 93453, 93456, 93457, 93458, 93459, 93460, 93461, 93593, 93594, 93595, 93596, 93597, 93598) and diagnostic coronary angiography codes (93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461, 93563, 93564) performed at the time of M-TEER or TMVR/TMVI may be separately reportable, if:

1. No prior study is available, and a full diagnostic study is performed, or
2. A prior study is available, but as documented in the medical record:

   a.) There is inadequate visualization of the anatomy and/or pathology, or

   b.) The patient's condition with respect to the clinical indication has changed since the prior study, or

   c.) There is a clinical change during the procedure that requires new evaluation.

For same session/same day diagnostic cardiac catheterization services, report the appropriate diagnostic cardiac catheterization code(s) appended with modifier -59, indicating separate and distinct procedural service from M-TEER or TMVR/TMVI.

Inpatient Hospital

Medicare inpatient hospital reimbursement is based upon the Medicare Severity Diagnostic Related Group (MS-DRG) classification system, which assigns MS-DRGs based on ICD-10-CM diagnoses and ICD-10-PCS procedure codes. This guide is limited to the reporting and billing of the surgical procedure.

All preoperative, postoperative, and follow-up services should be billed according to the service performed in conjunction with standard billing and coding guidelines.

The following details ICD-10-PCS coding and the applicable FY2026 MS-DRG assignment for implantation of the PASCAL Precision system and SAPIEN M3 system. The code reported for the procedure must be supported by the medical record documentation.

Medicare Severity Diagnostic Related Groups (MS-DRG)

MS-DRG	Description	FY2026 Relative Weight[5]	FY2026 Medicare National Unadjusted Base Payment[5]	FY2026 Geometric Mean LOS[5]
266	Endovascular cardiac valve replacement and supplement procedures with MCC	6.1284	$44,595	2.5
267	Endovascular cardiac valve replacement and supplement procedures without MCC	4.7608	$34,643	1.3

FY2026 payment rates effective October 1, 2025 – September 30, 2026.

ICD-10-PCS Procedure Codes[2,6]

ICD-10PCS Code	Description
PASCAL Precision system (M-TEER)	
02UG3JZ	Supplement mitral valve with synthetic substitute, percutaneous approach
SAPIEN M3 system (TMVR/TMVI)	
02RG38Z	Replacement of Mitral Valve with Zooplastic Tissue, Percutaneous Approach

Revenue code

Revenue Code	Description
278	Medical/surgical supplies and devices; other implants

Additional notes for the PASCAL Precision system inpatient hospital billing:

- Medicare will only pay for claims for ICD-10-PCS code 02UG3JZ when billed with the following:[4]
- ICD-10-CM diagnosis codes I34.0 or I34.1 and ICD-10-CM secondary diagnosis code Z00.6 (encounter for examination for normal comparison and control in clinical research program)
- National Clinical Trial (NCT) number (e.g., the NCT number for the TVT Registry Mitral Module is 02245763). For Form CMS-1450 paper claims, enter 02245763 in the value amount, value code D4. For 8371i electronic claims, enter 02245763 in Loop 2300 REF02 (REF01 = P4)
- Condition code 30
- Revenue code 278 (medical/surgical supplies and devices: other implants)

Medicare will return all other claims as not processable.

Diagnosis Codes

ICD-10-CM Diagnosis Codes[7]

Potential ICD-10-CM Codes	Description
PASCAL Precision system (M-TEER)	
I34.0	Non-rheumatic mitral (valve) insufficiency
I34.1	Non-rheumatic mitral (valve) prolapse
Z00.6	Encounter for exam for normal comparison and control in clinical research program
SAPIEN M3 system (TMVR/TMVI)	
I05.0	Rheumatic mitral stenosis
I05.1	Rheumatic mitral insufficiency
I05.2	Rheumatic mitral stenosis with insufficiency
I05.8	Other rheumatic mitral valve diseases
I05.9	Rheumatic mitral valve disease, unspecified
I34.0	Non-rheumatic mitral (valve) insufficiency
I34.1	Non-rheumatic mitral (valve) prolapse
I34.2	Non-rheumatic mitral (valve) stenosis
I34.81	Nonrheumatic mitral (valve) annulus calcification
I34.89	Other nonrheumatic mitral valve disorders
I34.9	Nonrheumatic mitral valve disorder, unspecified

Outpatient Hospital

Hospitals use CPT codes when billing for procedures in the outpatient setting. Medicare pays for many procedures performed in the outpatient hospital setting under a prospective payment system. However, Medicare does not reimburse for outpatient services they do not believe may be safely done in the outpatient hospital setting for their patient population. CMS has designated both M-TEER and TMVR/TMVI procedures as inpatient only.

Commercial Payer

Each non-Medicare payer has its own methodology for paying providers. Check with the patient's payer medical policy and your payer contracts to determine potential payments and if the procedure will be covered. The best way to determine if the procedure will be covered is to submit a preauthorization/pre-determination request to the patient's payer prior to scheduling the surgery.

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Important Safety Information

Edwards PASCAL Precision Transcatheter Valve Repair System

Indications: The PASCAL Precision transcatheter valve repair system (the PASCAL Precision system) is indicated for the percutaneous reduction of significant, symptomatic mitral regurgitation (MR ≥3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the MR.

Contraindications: The PASCAL Precision system is contraindicated in patients with the following conditions: patients who cannot tolerate procedural anticoagulation or post-procedural anti-platelet regimen; untreatable hypersensitivity or contraindication to nitinol alloys (nickel and titanium) or contrast media; active endocarditis of the mitral valve; rheumatic etiology for mitral regurgitation; evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus.

Warnings: The devices are designed, intended, and distributed for single use only. There are no data to support the sterility, non-pyrogenicity, and functionality of the devices after reprocessing. Devices should be handled using standard sterile technique to prevent infection. Do not expose any of the devices to any solutions, chemicals, etc., except for the sterile physiological and/or heparinized saline solution. Irreparable damage to the device, which may not be apparent under visual inspection, may result. Do not use any of the devices in the presence of combustible or flammable gases, anesthetics, or cleaners/disinfectants. Do not use the devices if the expiration date has elapsed. Do not use if the packaging seal is broken or if the packaging is damaged for sterile devices. Do not use if any of the devices were dropped, damaged or mishandled in any way. Standard flushing and de-airing technique should be used during preparation and throughout procedure to prevent air embolism.

As with any implanted medical device, there is a potential for an adverse immunological response. Serious adverse events, sometimes leading to surgical intervention and/or death, may be associated with the use of this system ("Potential Adverse Events"). A full explanation of the benefits and risks should be given to each prospective patient before use. Careful and continuous medical follow-up is advised so that implant-related complications can be diagnosed and properly managed. Anticoagulation therapy must be determined by the physician per institutional guidelines.

Precautions: Prior to use, patient selection should be performed by a heart team to assess patient risk and anatomical suitability. After use, short-term anticoagulation therapy may be necessary after valve repair with the PASCAL Precision system. Prescribe anticoagulation and other medical therapy per institutional guidelines.

Potential Adverse Events: Below is a list of the potential adverse effects (e.g., complications) associated with the use of the PASCAL Precision system: death; abnormal lab values; allergic reaction to anesthetic, contrast, heparin, Nitinol; anemia or decreased hemoglobin (may require transfusion); aneurysm or pseudoaneurysm; angina or chest pain; anaphylactic shock; arrhythmias - atrial (i.e. atrial fibrillation, Supraventricular tachycardia); arrhythmias - ventricular (i.e. ventricular tachycardia, ventricular fibrillation); arterio-venous fistula; atrial septal injury requiring intervention; bleeding; cardiac arrest; cardiac failure; cardiac injury, including perforation; cardiac tamponade/pericardial effusion; cardiogenic shock; chordal entanglement or rupture that may require intervention; coagulopathy, coagulation disorder, bleeding diathesis; conduction system injury which may require permanent pacemaker; deep vein thrombosis (DVT); deterioration of native valve (e.g. leaflet tearing, retraction, thickening); dislodgement of previously deployed implant; dyspnea; edema; electrolyte imbalance; emboli/embolization including air, particulate, calcific material, or thrombus; endocarditis; esophageal irritation; esophageal perforation or stricture; exercise intolerance or weakness; failure to retrieve any PASCAL Precision system components; fever; gastrointestinal bleeding or infarct; heart failure; hematoma; hemodynamic compromise; hemolysis; hemorrhage requiring transfusion or intervention; hypertension; hypotension; implant deterioration (wear, tear, fracture, or other); implant embolization; implant malposition or failure to deliver to intended site; implant migration; implant thrombosis; infection; inflammation; LVOT obstruction; mesenteric ischemia; multi-system organ failure; myocardial infarction; native valve injury; native valve stenosis; nausea and/or vomiting; need for open surgery (conversion, emergent or nonemergent reoperation, explant), nerve injury neurological symptoms, including dyskinesia, without diagnosis of TIA or stroke; non-neurological thromboembolic events; pain; papillary muscle damage; paralysis; PASCAL Precision system component(s) embolization; peripheral ischemia; permanent disability; pleural effusion; pulmonary edema; pulmonary embolism; reaction to anti-platelet or anticoagulation agents; renal failure; renal insufficiency; respiratory compromise, respiratory failure, atelectasis, pneumonia - may require prolonged ventilation; retroperitoneal bleed; septal damage or perforation; septicemia, sepsis; skin burn, injury or tissue changes due to exposure to ionizing radiation; single leaflet device attachment (SLDA); stroke; syncope; transient

ischemic attack (TIA); urinary tract infection and/or bleeding; valvular regurgitation; vascular injury or trauma, including dissection or occlusion; vessel spasm; ventricular wall damage or perforation; worsening native valve regurgitation / valvular insufficiency; worsening of heart failure; wound dehiscence, delayed or incomplete healing.

Edwards Reusable Accessories

Indications: The Edwards reusable platform, reusable plate, and reusable cradle are reusable, non-sterile accessories indicated for use with compatible Edwards transcatheter cardiac therapies. The reusable platform and reusable plate are non-patient contacting and are intended to aid the positioning and stabilization of delivery systems during intra-cardiac procedures.

Contraindications: There are no specific contraindications for these accessories.

Warnings: There are no warnings specific to these accessories.

Precautions: The reusable platform, reusable plate, and reusable cradle are NON-STERILE; introduction of the reusable platform, reusable plate, and reusable cradle into the sterile field may result in infection. Prior to use, cleaning must be performed according to the Edwards Reusable Accessories Instructions for Use. Do not use metallic brushes, scrub pads, or other abrasive cleaning aids when cleaning the devices. They can cause permanent device damage.

Potential Adverse Events: There are no known potential adverse events specific to the Edwards reusable platform, reusable plate, or reusable cradle.

CAUTION: Federal (United States) law restricts these devices to s ale by or on the order of a physician. See instructions for use for full prescribing information.

SAPIEN M3 Transcatheter Mitral Valve Replacement System- Important Safety Information

Indications: The SAPIEN M3 transcatheter mitral valve replacement system (SAPIEN M3 system) is indicated for the treatment of symptomatic moderate-to-severe or severe mitral regurgitation (MR) in patients who are deemed unsuitable for surgery or transcatheter edge-to-edge repair (TEER) therapy by a multidisciplinary heart team. The SAPIEN M3 system is also indicated for the treatment of symptomatic mitral valve dysfunction (moderate-to-severe or severe MR, severe mitral stenosis (MS), or moderate MR with moderate MS) associated with mitral annular calcification (MAC) in patients who are deemed unsuitable for surgery or TEER therapy by a multidisciplinary heart team. The Edwards 23F guide sheath is indicated to provide venous vascular access to cardiac structures enabling the introduction and removal of SAPIEN M3 transcatheter mitral valve replacement devices.

Contraindications: The SAPIEN M3 system is contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or intraprocedural heparin, or who have active bacterial endocarditis or other active infections.

Warnings: The SAPIEN M3 system devices and Edwards 23F guide sheath are designed, intended, and distributed STERILE for single use only. Do not resterilize or reuse the devices. There are no data to support the sterility, non-pyrogenicity, and functionality of the devices after reprocessing. Do not mishandle the SAPIEN M3 system devices or use them if the packaging or any components are not sterile, have been opened or are damaged (e.g., kinked or stretched), or the expiration date has elapsed. Patients with hypersensitivities to cobalt, nitinol (nickel or titanium), chromium, molybdenum, manganese, silicon, bovine tissue, and/or polymeric materials may have an allergic reaction/immunological response to these materials. Accelerated deterioration of the valve may occur in patients with altered calcium metabolism. Exercise caution when implanting a valve in patients with clinically significant coronary artery disease as it may result in myocardial ischemia. Prior to delivery, the valve must always remain hydrated and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Valve leaflets mishandled or damaged during any part of the procedure will require replacement of the valve. Do not use the valve if the tamper-evident seal is broken, the storage solution does not completely cover the valve, the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed. Do not add or apply antibiotics to the storage solution, rinse solutions, or the valve. The physician must verify correct orientation of the valve prior to its implantation. The procedure should be conducted under 3D echocardiography and fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting. Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored. Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation. In the event of device malfunction or device damage during use (e.g., destructive deformation to the catheter, balloon burst, etc.) safely remove the device(s). If unable to safely remove the device(s), conversion to surgery is recommended. Prior to valve deployment, 3D echocardiographic and fluoroscopic (short-axis view) verification must be used to confirm that the guidewire passes through the center of the implanted dock and has unrestricted movement. Failure to do so can result in chordal rupture and/or the valve being deployed

outside of target location. Incorrect positioning of the dock and/or valve may lead to left ventricular outflow tract obstruction, paravalvular leak (PVL), valve migration, or valve embolization. Valve recipients must be on appropriate anticoagulation regimen, determined at the physician's discretion based on individual subject needs for a minimum of 6 months. Failure to anticoagulate and bridge appropriately will lead to valve thrombosis. For subjects receiving vitamin K antagonists, target range for INR is 2.5 to 3.5. After 6 months, continued antithrombotic therapy is recommended as tolerated. Characteristics of the device(s) to be inserted into the guide sheath should be evaluated to prevent damage to the interior liner of the guide sheath, damage to the device(s) being inserted, and/or injury to the patient. Patient injury could occur if the guide sheath is not unflexed prior to removal. In the event of device malfunction or device damage during use (e.g. destructive deformation to the catheter) safely remove the device(s). If unable to safely remove the device(s), conversion to surgery is recommended.

Precautions: Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Material Safety Data Sheet available from Edwards Lifesciences. Additional precautions for transseptal replacement of a mitral valve include abnormalities in the caval vein precluding safe transvenous femoral access for transseptal approach, presence of atrial septal occluder device, or calcium preventing safe transseptal access. Use caution in tortuous or calcified vessels that would prevent safe entry of the guide sheath and introducer. Patients with a pre-existing prosthesis should be evaluated for the location, shape, construction, and characteristics of the prosthesis (e.g., low-deployed aortic prosthesis, rigid or small annuloplasty ring, septal occluder, etc.) as it may interfere with SAPIEN M3 system deployment, functionality, or dock/valve durability. Patients with mitral annular calcification should be evaluated for the characteristics of the calcium and mitral pathology as it may interfere with the dock trajectory during deployment, result in malposition of the dock/valve, and/or have an increased risk of PVL. Patient's sub-valvular anatomy should be evaluated for the characteristics of papillary muscles, chordae, and ventricular wall as it may interfere with or prevent dock deployment. Patients with the following characteristics have an increased risk of PVL which may lead to hemolysis and/or intervention: compromised leaflet integrity (e.g., perforation, endocarditis, Barlow's syndrome, etc.); flail or prolapse located at the commissures; flail or prolapse located at P3 leaflet in conjunction with a commissural distance ≥ 42mm; Any large non-commissural flail or prolapse. The sheath and introducer are coated with a hydrophilic lubricious coating. Failure to activate the hydrophilic coating with heparinized saline may result in difficulty with insertion. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance. The safety and effectiveness of the SAPIEN M3 system have not been established for patients who have/are: a left ventricular end-diastolic diameter ≥ 75 mm; a commissural distance ≥50 mm; a left ventricular ejection fraction below 25%; severe RV dysfunction; History of heart transplant; Severe pulmonary hypertension; Blood dyscrasias defined as: leukopenia (WBC < 3000 cells/μL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 50,000 cells/μL), or history of bleeding diathesis or coagulopathy.

Potential Adverse Events: Potential risks associated with the anesthesia, interventional procedure, and imaging include but are not limited to: death; stroke or other neurological dysfunction; cardiovascular injury such as cardiac structure complications, vascular complications, and access related complications; heart failure or low cardiac output / worsening of heart failure; renal insufficiency or renal failure; cardiogenic shock; cardiac arrest; pericardial effusion or cardiac tamponade; thromboembolism including air, calcific valve material, or thrombus; retroperitoneal bleed; arrhythmia; hypertension or hypotension; new or worsening valvular regurgitation; bleeding / hematoma / hemorrhage; hemolysis that may require transfusion or intervention; device/valve thrombosis; respiratory insufficiency or respiratory failure; paravalvular or transvalvular leak; device deterioration (wear, fracture, calcification, or other) reoperation / reintervention; device explants; pleural effusion; LVOT obstruction; emergency cardiac surgery; conversion to cardiac surgery; thoracic bleeding; valve stenosis; myocardial infarction; pulmonary edema; transient ischemic attack including clusters; device migration, malposition or embolization; infection including septicemia and endocarditis; allergic reaction to anesthesia, contrast media, or device material; deterioration of native valve (leaflet tear/tearing, leaflet retraction, leaflet thickening, or other); structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of a prosthetic valve, thickening, stenosis); nonstructural valve dysfunction; atrial septal defect; syncope; dock wear or fracture; conduction system defect which may require a permanent pacemaker; skin burn; mechanical failure of delivery system, and/or accessories; valve deployment in an unintended location; abnormal lab values (including electrolyte imbalance); angina; anemia; stroke/TIA or nerve injury; vessel spasm; and catheter entrapment; fever; inflammation; pain or changes at the access site.

CAUTION: US law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information.

References

1. 1. Current Procedure Terminology (CPT) 2026 copyright 2025, American Medical Association (AMA). All rights reserved. CPT is a registered trademark of the AMA. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Applicable FARS/DFARS restrictions apply to government use.
2. Not all codes provided are applicable for the clinical scenarios in which Edwards Lifesciences' technologies are used. The provider is responsible for selecting the most appropriate code(s) for the patient's clinical presentation. When diagnostic services are performed, it may be appropriate to add applicable codes according to the service provided following the correct coding guidelines. Services that are considered a component of another procedure may not always be coded and billed separately.
3. CY 2026 Medicare Physician Fee Schedule Final Rule (CMS-1832-F); Addendum B, Nov. 5, 2025, Payments are effective January 1 - December 31, 2026. Non-Qualifying Physician Conversion factor: $33.4009. Qualifying Physician Conversion factor on January 1, 2026: $33.5675.
4. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual; Chapter 32 Billing Requirements for Special Services. Section 340
5. FY 2026 CMS Inpatient Prospective Payment System (IPPS) Final Rule (CMS-1833-F). Payments are effective October 1, 2025, through September 30, 2026.
6. 2026 ICD-10-PCS Code Tables and Tabular and Index https://www.cms.gov/medicare/coding-billing/icd-10-codes
7. 2026 ICD-10-CM Code Tables, Tabular and Index https://www.cms.gov/medicare/coding-billing/icd-10-codes

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