2024 Physician and Facility Billing Guide
Transcatheter Heart Valve Replacement Technologies

Disclaimer
Important – Please Note:

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Transcatheter Heart Valve Replacement Technologies
Physician Billing Codes

Physicians use Current Procedural Terminology (CPT)[1] 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 transcatheter aortic valve replacement (TAVR) and transcatheter pulmonary valve replacement (TPVR) procedures.

CY 2024 payment was calculated with the Conversion Factor (CF) of $33.2875. This new physician fee schedule only applies to claims with dates of service on or after March 9th, 2024.

Potential CPT Code	Description	CY2024 Medicare National Avg. Physician Payment[2]	Each Physician Payment (Modifier-62)	CY2024 Facility RVUs[2]
Transcatheter Aortic Valve Replacement (TAVR) and Transcatheter Aortic Valve-In-Valve Replacement[3]				
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	$1,179	$737	35.42
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach	$1,285	$803	38.60
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach	$1,333	$833	40.06
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach	$1,328	$830	39.88
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)	$1,389	$868	41.73
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy)	$1,529	$955	45.92

continued

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Potential CPT Code	Description	CY2024 Medicare National Avg. Physician Payment	Each Physician Payment (Modifier-62)	CY2024 Facility RVUs
TAVR Add-on Codes for Cardiopulmonary Bypass Support				
+33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., femoral vessels) (list separately in addition to code for primary procedure)	$592	NA	17.79
+33368	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (e.g., femoral, iliac, axillary vessels) (list separately in addition to code for primary procedure)	$718	NA	21.56
+33369	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (e.g., aorta, right atrium, pulmonary artery) (list separately in addition to code for primary procedure)	$947	NA	28.46
Unlisted Code for Alternative TAVR Approach (e.g. transcaval, subclavian, transcarotid)				
33999	Unlisted procedure, cardiac surgery	*Code should be submitted with a crosswalk code similar in scope and complexity to the unlisted procedure being performed.*		

Additional Notes for Physician Inpatient Coding for TAVR and Transcatheter Aortic Valve-in-Valve

Medicare will only pay TAVR physician claims for CPT codes 33361 – 33366 when billed with the following:[4]*

- Place of service (POS) code 21 (inpatient hospital)
- Modifier 62 (two surgeons/co-surgeons)
- Modifier Q0 (zero) signifying CED participation (qualifying registry or qualified clinical study)
- ICD-10 secondary diagnosis code Z00.6 (encounter for examination for normal comparison and control in clinical research program)
- Clinical Trial (CT) number (e.g. the CT number for the TVT Registry is NCT01737528)

** Medicare will return all other claims as unprocessable*

Notes:

- *As per American Medical Association (AMA) requirements for TAVR, TAVR is a two-physician (IC & CS) procedure. Payment for each physician is 62.5% of the established Medicare payment. Modifier 62 (co-surgeons) is not allowed for TAVR add-on codes 33367-33369.*
- *TAVR Codes 33361-33366 have a 0-day global period and do not include cardiac catheterization when performed at the time of the procedure for diagnostic purposes prior to aortic valve replacement.*
- *TAVR Codes 33361 - 33366 include all other catheterization[s], temporary pacing, intraprocedural contrast injection[s], fluoroscopic radiological supervision and interpretation, and imaging guidance, which are not reported separately when performed to complete the aortic valve procedure.*

Potential CPT Code	Description	CY2024 Medicare National Avg. Physician Payment	CY2024 Facility RVUs
Transcatheter Mitral Valve-in-Valve (MViV) Replacement[5] & Transcatheter Mitral Valve-in-Ring (MViR)			
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*
0484T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; transthoracic exposure (eg, thoracotomy, transapical)	*Based on carrier discretion*	*RVUs are not assigned*
Transcatheter Pulmonary Valve Replacement (TPVR)			
33477	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed	$1,277	38.37

Transcatheter Heart Valve Replacement Technologies

Inpatient Hospital Billing DRGs[6]

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 diagnosis and procedure codes. Pursuant to the final rule for the FY2020 hospital Inpatient Prospective Payment System (IPPS), CMS modified MS-DRGs for endovascular cardiac valve replacements to include supplement procedures, effective October 1, 2020. The following MS-DRGs generally describe hospital inpatient reimbursement for endovascular cardiac valve replacement and supplement procedures, including TAVR, TPVR, MViR and MViV procedures.

MS-DRG	Description	FY2024 Relative Weight	FY2024 Medicare National Average Base Payment	FY2024 Geometric Mean LOS
Endovascular Cardiac Valve Replacement Procedures				
266	Endovascular cardiac valve replacement and supplement procedures with MCC	6.2461	$43,733	2.7
267	Endovascular cardiac valve replacement and supplement procedures without MCC	4.8802	$34,169	1.3

Note: GMLOS based on FY2022 data provided in the FY2024 IPPS Final Rule, Table 5.

ICD – 10 – PCS[7] Procedure Codes for Inpatient Hospital Billing

Potential ICD-10-Procedure Code	Description
Transcatheter Aortic Valve Replacement (TAVR) and Transcatheter Aortic Valve-in-Valve (failed aortic surgical or transcatheter bioprosthetic)	
02RF38Z	Replacement of aortic valve with zooplastic tissue, percutaneous approach
02RF38H	Replacement of aortic valve with zooplastic tissue, transapical, percutaneous approach

Medicare will only pay TAVR Hospital claims for ICD-10-PCS codes 02RF38Z and 02RF38H when billed with the following*

- ICD-10 secondary diagnosis code Z00.6 (encounter for examination for normal comparison and control in clinical research program)
- Clinical Trial (CT) number (e.g. the CT number for the TVT Registry is NCT01737528)

* Medicare will return all other claims as unprocessable

Transcatheter Mitral Valve-in-Valve (MViV) & Transcatheter Mitral Valve-in-Ring (MViR)	
02RG38Z	Replacement of mitral valve with zooplastic tissue, percutaneous approach
02RG38H	Replacement of mitral valve with zooplastic tissue, transapical, percutaneous approach
Transcatheter Pulmonary Valve Replacement (TPVR)	
02RH38Z	Replacement of pulmonary valve with zooplastic tissue, percutaneous approach
02RH38M	Replacement of pulmonary valve with zooplastic tissue, native site, percutaneous approach

ICD – 10 – CM Diagnosis Codes[7]

Potential ICD-10-Diagnosis Code	Description	*ICD-10-CM Diagnosis codes included are intended to be a sample of commonly billed codes and should not be considered a complete list.*
Aortic Stenosis		
I35.0	Nonrheumatic aortic (valve) stenosis	
Z00.6	Encounter for examination for normal comparison and control in a clinical research program	
Bicuspid Valve		
Q23.0	Congenital stenosis of the aortic valve	
Transcatheter Valve-in-Valve or Transcatheter Mitral Valve-in-Ring (failed aortic surgical or transcatheter bioprosthetic, failed mitral surgical bioprosthetic, failed mitral surgical ring , or failed pulmonic surgical bioprosthetic)		
T82.222A	Displacement of biological heart valve graft, initial encounter	
T82.857A	Stenosis of cardiac prosthetic devices, implants and grafts, initial encounter	
T82.223A	Leakage of biological heart valve graft, initial encounter	
Transcatheter Pulmonary Valve Replacement (TPVR) Congenital Malformations		
Q20.0	Common arterial trunk	
Q20.1	Double outlet right ventricle	
Q20.3	Discordant ventriculoarterial connection	
Q20.5	Discordant atrioventricular connection	
Q21.3	Tetralogy of Fallot	
Q22.0	Pulmonary valve atresia	
Q22.1	Congenital pulmonary valve stenosis	
Q22.2	Congenital pulmonary valve insufficiency	
Q22.3	Other congenital malformations of pulmonary valve	
Q25.5	Atresia of pulmonary artery	
Q25.6	Stenosis of pulmonary artery	
Q25.71	Coarctation of pulmonary artery	
Q25.72	Congenital pulmonary arteriovenous malformation	
Q25.79	Other congenital malformations of pulmonary artery	

Outpatient Hospital Billing

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 maybe safely done in the outpatient hospital setting for their patient population. CMS has designated transcatheter heart valve procedures to be inpatient only procedures, meaning the hospital will not receive payment from Medicare should it be performed in an outpatient setting. HCPCS C-Codes are only used for Medicare hospital outpatient claims, therefore a HCPCS C-Code does not exist for the Edwards Transcatheter Valve Systems.

Commercial Payer Billing

Each non-Medicare payer has its own methodology for paying providers. Edwards recommends checking 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.

Important Safety Information

Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Indications: The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for patients with symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic valve, a surgical bioprosthetic mitral valve, or a native mitral valve with an annuloplasty ring who are judged by a Heart Team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications: The valves and delivery systems are contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections, or who have significant annuloplasty ring dehiscence.

Warnings: Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation. There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments in high or greater risk patients. The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. Incorrect sizing of the valve may lead to paravalvular leak, migration, embolization, residual gradient (patient-prosthesis mismatch), and/or annular rupture. Accelerated deterioration of the valve due to calcific degeneration may occur in children, adolescents, or young adults and in patients with an altered calcium metabolism. Prior to delivery, the valve must remain hydrated at all times 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. Caution should be exercised in implanting a valve in patients with clinically significant coronary artery disease. Patients with pre-existing prostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment. Do not use the valve if the tamper-evident seal is broken or the storage solution does not completely cover the valve (SAPIEN 3 and SAPIEN 3 Ultra only), the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed. Do not mishandle the delivery system or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g., kinked or stretched), or if the expiration date has elapsed. 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. Patient injury could occur if the delivery system is not un-flexed prior to removal. Care should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be conducted under 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. Valve recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, as determined by their physician. This device has not been tested for use without anticoagulation. Do not add or apply antibiotics to the storage solution (SAPIEN 3 and SAPIEN 3 Ultra only), rinse solution, or to the valve. Balloon valvuloplasty should be avoided in the treatment of failing bioprostheses as this may result in embolization of bioprosthesis material and mechanical disruption of the valve leaflets. Do not perform stand-alone balloon aortic valvuloplasty procedures in the INSPIRIS RESILIA aortic valve for the sizes 19-25 mm. This may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of partial annuloplasty ring dehiscence due to high risk of PVL. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of partial (incomplete) annuloplasty rings in the absence of annular calcium due to increased risk of valve embolization. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of rigid annuloplasty rings due to increased risk of PVL or THV deformation.

Precautions: Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance. Limited clinical data are available for transcatheter aortic valve replacement in patients with a congenital bicuspid aortic valve who are deemed to be at low surgical risk. Anatomical characteristics should be considered when using the valve in this population. In addition, patient age should be considered as long-term durability of the valve has not been established. 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 Safety Data Sheet available from Edwards Lifesciences. If a significant increase in resistance occurs when advancing the catheter through the vasculature, stop advancement and investigate the cause of resistance before proceeding. Do not force passage, as this could increase the risk of vascular complications. As compared to SAPIEN 3, system advancement force may be higher with the use of SAPIEN 3 Ultra/SAPIEN 3 Ultra RESILIA THV in tortuous/challenging vessel anatomies. 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. Additional precautions for transseptal replacement of a failed mitral valve bioprosthesis include, the presence of devices or thrombus or other abnormalities in the caval vein precluding safe transvenous femoral access for transseptal approach; and the presence of an Atrial Septal Occluder Device or calcium preventing safe transseptal access. Special care must be exercised in mitral valve replacement to avoid entrapment of the subvalvular apparatus. Safety and effectiveness have not been established for patients with the

following characteristics/comorbidities: non-calcified aortic annulus; severe ventricular dysfunction with ejection fraction < 20%; congenital unicuspid aortic valve; pre-existing prosthetic ring in the tricuspid position; severe mitral annular calcification (MAC); severe (> 3+) mitral insufficiency, or Gorlin syndrome; blood dyscrasias defined as leukopenia (WBC < 3000 cells/mL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 50,000 cells/mL), or history of bleeding diathesis or coagulopathy; hypertrophic cardiomyopathy with or without obstruction (HOCM); echocardiographic evidence of intracardiac mass, thrombus, or vegetation; a known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media, which cannot be adequately premedicated; significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater, marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding, or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta; access characteristics that would preclude safe placement of the Edwards sheath, such as severe obstructive calcification or severe tortuosity; bulky calcified aortic valve leaflets in close proximity to coronary ostia; a concomitant paravalvular leak where the failing prosthesis is not securely fixed in the native annulus or is not structurally intact (e.g., wireform frame fracture, annuloplasty ring dehiscence); or a partially detached leaflet of the failing bioprosthesis that in the aortic position may obstruct a coronary ostium. For Left axillary approach, a left subclavian takeoff angle ~ ≥ 90° from the aortic arch causes sharp angles, which may be responsible for potential sheath kinking, subclavian/axillary dissection and aortic arch damage. For left/right axillary approach, ensure there is flow in Left Internal Mammary Artery (LIMA)/Right Internal Mammary Artery (RIMA) during procedure and monitor pressure in homolateral radial artery. Residual mean gradient may be higher in a "THV-in-failing prosthesis" configuration than that observed following implantation of the valve inside a native aortic annulus using the same size device. Patients with elevated mean gradient post procedure should be carefully followed. It is important that the manufacturer, model and size of the preexisting prosthesis be determined, so that the appropriate valve can be implanted and a prosthesis-patient mismatch be avoided. Additionally, pre-procedure imaging modalities must be employed to make as accurate a determination of the inner diameter as possible.

Potential Adverse Events: Potential risks associated with the overall procedure, including potential access complications associated with standard cardiac catheterization, balloon valvuloplasty, the potential risks of conscious sedation and/or general anesthesia, and the use of angiography: death; stroke/transient ischemic attack, clusters, or neurological deficit; paralysis; permanent disability; respiratory insufficiency or respiratory failure; hemorrhage requiring transfusion or intervention; cardiovascular injury including perforation or dissection of vessels, ventricle, atrium, septum, myocardium, or valvular structures that may require intervention; pericardial effusion or cardiac tamponade; thoracic bleeding; embolization including air, calcific valve material, or thrombus; infection including septicemia and endocarditis; heart failure; myocardial infarction; renal insufficiency or renal failure; conduction system defect which may require a permanent pacemaker; arrhythmia; retroperitoneal bleed; arteriovenous (AV) fistula or pseudoaneurysm; reoperation; ischemia or nerve injury or brachial plexus injury; restenosis; pulmonary edema; pleural effusion; bleeding; anemia; abnormal lab values (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia, contrast media, or device materials; hematoma; syncope; pain or changes (e.g., wound infection, hematoma, and other wound care complications) at the access site; exercise intolerance or weakness; inflammation; angina; heart murmur; and fever. Additional potential risks associated with the use of the valve, delivery system, and/or accessories include: cardiac arrest; cardiogenic shock; emergency cardiac surgery; cardiac failure or low cardiac output; coronary flow obstruction/transvalvular flow disturbance; device thrombosis requiring intervention; valve thrombosis; device embolization; device migration or malposition requiring intervention; left ventricular outflow tract obstruction; valve deployment in unintended location; valve stenosis; 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); device degeneration; paravalvular or transvalvular leak; valve regurgitation; hemolysis; device explants; nonstructural dysfunction; mechanical failure of delivery system and/or accessories; and non-emergent reoperation.

Edwards Crimper

Indications: The Edwards crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve, Edwards SAPIEN 3 Ultra transcatheter heart valve, and the Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve for implantation.

Contraindications: There are no known contraindications.

Warnings: The device is designed, intended, and distributed for single use only. **Do not resterilize or reuse the device.** There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Do not mishandle the device. Do not use the device if the packaging or any components are not sterile, have been opened or are damaged, or the expiration date has elapsed.

Precautions: For special considerations associated with the use of the Edwards crimper prior to THV implantation, refer to the THV Instructions for Use.

Potential Adverse Events: There are no known potential adverse events associated with the Edwards crimper.

Edwards SAPIEN 3 Transcatheter Heart Valve System – Pulmonic

Indications: The Edwards SAPIEN 3 Transcatheter Heart Valve (THV) System with Edwards Commander Delivery System is indicated for use in the management of pediatric and adult patients who have a clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic valve in the pulmonic position with ≥ moderate regurgitation and/or a mean RVOT gradient of ≥ 35 mmHg.

Contraindications: The Edwards SAPIEN 3 THV System with Edwards Commander Delivery System is contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices**. There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. Correct sizing of the valve into the non-compliant RVOT conduit or failing bioprosthesis (landing zone) is essential to minimize risks. Too small of a valve may result in paravalvular leak, migration, or valve embolization; whereas too large of a valve may result in residual gradient (patient-prosthesis mismatch) or RVOT rupture. Accelerated deterioration of the valve may occur in patients with an altered calcium metabolism. Assessment for coronary compression risk prior to valve implantation is essential to prevent the risk of severe patient harm. The physician must verify correct orientation of the valve prior to its implantation; the inflow (outer skirt end) of the valve should be oriented toward the proximal end (handle) of the delivery system to prevent the risk of severe patient harm. Prior to delivery, the valve must remain hydrated at all times 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. Patients with pre-existing bioprostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment. 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 mishandle the delivery system or use it 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. 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. Patient injury could occur if the delivery system is not un-flexed prior to removal. Care should be exercised in patients with

hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be conducted under 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. It is recommended that all prosthetic heart valve recipients be prophylactically treated for endocarditis to minimize the possibility of prosthetic valve infection. Valve recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, as determined by their physician. This device has not been tested for use without anticoagulation. Do not add or apply antibiotics to the storage solution, rinse solutions or to the valve.

Precautions: Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance. 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. 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. Patient venous anatomy should be evaluated to prevent the risk of access that would preclude the delivery and deployment of the device. Patient should be heparinized to maintain the ACT at ≥ 250 sec prior to introduction of the delivery system in order to prevent thrombosis. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: Blood dyscrasias defined as: leukopenia, acute anemia, thrombocytopenia, or history of bleeding diathesis or coagulopathy. A known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid™), or clopidogrel (Plavix™), or sensitivity to contrast media, which cannot be adequately premedicated. Positive urine or serum pregnancy test in female subjects of child-bearing potential. Residual mean gradient may be higher in a "THV-in-failing bioprosthesis" configuration than that observed following implantation of the valve inside a native annulus using the same size device. Patients with elevated mean gradient post procedure should be carefully followed. It is important that the manufacturer, model and size of the preexisting bioprosthetic valve be determined, so that the appropriate valve can be implanted and a prosthesis-patient mismatch be avoided. Additionally, pre-procedure imaging modalities must be employed to make as accurate a determination of the inner diameter as possible.

Potential Adverse Events: Potential risks associated with the anesthesia, interventional procedure and imaging include but are not limited to: death; stroke/transient ischemic attack; respiratory insufficiency or respiratory failure; cardiovascular or vascular injury, such as perforation or damage (dissection) of vessels, myocardium or valvular structures including rupture of the RVOT that may require intervention; pericardial effusion/cardiac tamponade; embolic event: air, calcific material, thrombus, device fragments; infection including incisional site infection, septicemia and endocarditis; myocardial infarction; renal insufficiency or renal failure; conduction system injury, arrhythmia, arteriovenous (AV) fistula; systemic or peripheral nerve injury, systemic or peripheral ischemia, pulmonary edema, pneumothorax, pleural effusion, atelectasis; blood loss requiring transfusion; anemia; radiation injury; electrolyte imbalance; hypertension or hypotension; allergic reaction to anesthesia, contrast media, antithrombotic therapy, device materials; hematoma or ecchymosis, syncope, pain, exercise intolerance or weakness, inflammation; angina; fever; cardiac failure. Potential risks associated with the valve, delivery system and/or accessories include, but may not be limited to, the following: cardiac arrest; cardiogenic shock; coronary flow obstruction/transvalvular flow disturbance, device thrombosis requiring intervention; injury to tricuspid valve; device embolization requiring intervention; device acute migration or malposition requiring intervention; endocarditis; hemolysis / hemolytic anemia; THV dysfunction resulting in pulmonary valve symptoms; mechanical failure of delivery system, and/or accessories; emergent and non-emergent re-intervention; dyspnea.

Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent

Indications: The Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation as measured by echocardiography who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for pulmonary valve replacement.

Contraindications: The Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent is contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. The physician must verify correct orientation of the valve prior to its implantation; the inflow (outer skirt end) of the valve should be oriented towards the proximal end (handle) of the delivery system to prevent the risk of severe patient harm. Prior to delivery, the valve must remain hydrated at all times 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 mishandle the delivery system or use it 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. Do not add or apply antibiotics to the storage solution, rinse solutions or to the valve.

Precautions: Long-term durability has not been established for the device. Regular medical follow-up is advised to evaluate device performance. Patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials may have an allergic reaction to these materials. Accelerated deterioration of the valve may occur in patients with an altered calcium metabolism. Assessment for coronary compression risk prior to implantation is recommended. Patient venous anatomy should be evaluated to prevent the risk of access that would preclude the delivery and deployment of the device. 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. Fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. Patient radiation dose should be monitored during the procedure. 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. Patient should be heparinized to maintain the ACT at ≥ 250 sec prior to introduction of the delivery system in order to prevent thrombosis. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Device recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, as determined by their physician. This device has not been tested for use without antiplatelet therapy. It is recommended that all device recipients be prophylactically treated for endocarditis to minimize the possibility of prosthetic valve infection. Correct sizing of the prestent into the RVOT is essential to minimize risks such as paravalvular leak, migration, embolization, and/or RVOT rupture. If a prestent fracture is detected with significant loss in valve functionality, reintervention should be considered. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: blood dyscrasias defined as: leukopenia, acute anemia, thrombocytopenia, or history of bleeding diathesis or coagulopathy; a known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid™), or clopidogrel (Plavix™), or sensitivity to contrast media, which cannot be adequately premedicated; positive urine or serum pregnancy test in female patients of child-bearing potential.

Potential Adverse Events: Potential risks associated with the anesthesia, interventional procedure, and imaging include but are not limited to death; stroke/transient ischemic attack; respiratory insufficiency or respiratory failure; cardiovascular or vascular injury, such as perforation or damage (dissection) of vessels, myocardium, or valvular structures, including rupture of the RVOT that may require intervention; pericardial effusion/cardiac tamponade; cardiac failure; embolic event: air, calcific material, thrombus, device fragments; infection, including incisional site infection, septicemia, and endocarditis; myocardial infarction; renal insufficiency or renal failure; conduction system injury; arrhythmia; deep vein thrombosis; arteriovenous (AV) fistula; systemic or peripheral nerve injury; systemic or peripheral ischemia; pulmonary edema; pneumothorax; pleural effusion; dyspnea; atelectasis; dislodgement of previously implanted devices (i.e. pacing lead); blood loss requiring transfusion; anemia; radiation injury; electrolyte imbalance; hypertension or hypotension; allergic reaction to anesthesia, contrast media, antithrombotic therapy, device materials; hematoma or ecchymosis; syncope; pain; exercise intolerance or weakness; inflammation; angina; fever. Potential risks, that may or may not require intervention, associated with the valve, prestent, delivery system, and/or accessories include, but may not be limited to, the following: cardiac arrest; cardiogenic shock; coronary flow obstruction/transvalvular flow disturbance; device thrombosis; injury to tricuspid valve; device fracture; device embolization; device acute migration or malposition; endocarditis; chest pain/discomfort; hemolysis/ hemolytic anemia; device penetration/perforation into surrounding vasculature; device dysfunction (regurgitation and/or stenosis); aortic root distortion; embolic events: device fragments; mechanical failure of delivery system, and/or accessories.

Edwards Crimper

Indications: The Edwards crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve for implantation.

Contraindications: There are no known contraindications.

Warnings: The device is designed, intended, and distributed for single use only. **Do not resterilize or reuse the device.** There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Do not mishandle the device. Do not use the device if the packaging or any components are not sterile, have been opened or are damaged, or the expiration date has elapsed.

Precautions: For special considerations associated with the use of the Edwards crimper prior to THV implantation, refer to the THV Instructions for Use.

Potential Adverse Events: There re no known potential adverse events associated with the Edwards crimper.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician.

References

1. Current Procedure Terminology (CPT) copyright 2023, 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. Centers or Medicare & Medicaid Services, CY2024 Physician Fee Schedule (MPFS) Final Rule. Conversion Factor (CF) update: Consolidated Appropriations Act 2024, effective March 9, 2024.
3. CPT Assistant January 2013, Volume 23 Issue 1.
4. Medicare Claims Processing Manual, Chapter 32, Section 290.
5. CPT Assistant December 2022, Volume 32, Issue 12.
6. Centers for Medicare & Medicaid Services. FY2024 Inpatient Prospective Payment System (IPPS) Final Rule. Payments are effective October 1, 2023 through September 30, 2024.
7. International Classification of Diseases, 10th Revision, Clinical Modification 2024 ICD-10-CM and PCS Expert for Hospitals, volume 1, 2, and 3.

- *Not all codes provided are applicable for the clinical scenarios in which Edwards Lifesciences' Transcatheter Heart Valve 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.*

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