2021 Physician and Facility Billing Guide
Transcatheter Heart Valve Replacement Technologies

Transcatheter Heart Valve Replacement Technologies
Physician Billing Codes

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 transcatheter aortic valve replacement (TAVR) and transcatheter pulmonary valve replacement (TPVR) procedures. Clinicians use CPT Category III codes to track the use of emerging technology, services, and procedures for clinical efficacy, utilization and outcomes, and to facilitate billing. Category III codes are temporary and do not have relative value units (RVUs) assigned to them unlike the "permanent" CPT Category I codes. Payment has not been established and is therefore based on carrier discretion rather than a yearly fee schedule. The American Medical Association (AMA) has released Category III codes for the use of transcatheter mitral valve valve-in-valve (TM-VIV) technology. When using Category III codes, clinicians are required to submit a paper claim along with an operative report describing the procedure in order to justify the clinician's fee. All providers should review the patient's plan/medical policy prior to scheduling surgery to ensure the payer does not have a non-coverage policy. Several payers have non-coverage for TM-VIV that are unrelated to Category III designation.

Potential CPT Code	Description	CY2021 Medicare National Avg. Physician Payment	Each Physician Payment (Modifier-62)	CY2021 Facility RVUs
Transcatheter Aortic Valve Replacement (TAVR)				
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	$1,233	$771	35.34
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach	$1,343	$839	38.50
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach	$1,393	$871	39.93
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach	$1,394	$871	39.95
33365	Transcatheter aortic valve replacement aortic approach (e.g., median sternotomy, (TAVR/TAVI) with prosthetic valve; transmediastinotomy)	$1,452	$908	41.62
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy)	$1,602	$1001	45.90

Edwards

Potential CPT Code	Description	CY2021 Medicare National Avg. Physician Payment	Each Physician Payment (Modifier-62)	CY2021 Facility RVUs
TAVR Add-on Codes				
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)	$640	NA	18.35
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)	$756	NA	21.66
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)	$998	NA	28.60
Unlisted Code for Alternative TAVR Approach (e.g. subcaval, subcaval, carotid)				
33399	Unlisted procedure cardiac surgery	*Code should be submitted with a TAVR crosswalk code (e.g. CPTs 33361 – 33366). Identify a crosswalk code of similar RVUs to the unlisted procedure being performed.*		

Additional Notes for Physician Inpatient Coding for TAVR

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

- 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 CT01737528)

** 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 national average payment. +33367,33368 and 33369 are add-on codes which do not require modifier 62 hence each physician payment of 62.5% does not apply.*
- *Codes 33361-33369 have a 0-day global period and do not include cardiac catheterization [93451-93572] when performed at the time of the procedure for diagnostic purposes prior to aortic valve replacement. Codes 33361 - 33369 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.*
- *Code also modifier 59 when diagnostic coronary angiography procedures are performed as separate and distinct procedural services on the same day or session as TAVR/TAVI*

Potential CPT Code	Description	CY2021 Medicare National Avg. Physician Payment	CY2021 Facility RVUs
Transcatheter Mitral Valve-in-Valve (TM-VIV)			
0483T Category III	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed	Based on carrier discretion	NA
0484T Category III	Transthoracic exposure (e.g.,thoracotomy, transapical)	Based on carrier discretion	NA
Transcatheter Pulmonary Valve Replacement (TPVR)			
33477	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed	$1,381	39.58

Note: CPTs 0483T, 0484T, and 33477 **do not require modifier 62** and a physician payment adjustment of 62.5% does not apply.

Transcatheter Heart Valve Replacement Technologies

Inpatient Hospital Billing DRGs

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 FY 2015 hospital Inpatient Prospective Payment System (IPPS), CMS created separate MS-DRGs for endovascular cardiac valve replacements, effective October 1, 2014. The following MS-DRGs generally describe hospital inpatient reimbursement for endovascular cardiac valve replacement procedures, including TAVR, TPVR, and TM-ViV procedures.

MS-DRG	Description	FY2021 Relative Weight	FY2021 Medicare National Average Base Payment	FY2021 Geometric Mean LOS
Endovascular Cardiac Valve Replacement Procedures				
266	Endovascular cardiac valve replacement and supplement procedures with MCC	7.0972	$45,617	3.2
267	Endovascular cardiac valve replacement and supplement procedures without MCC	5.6009	$36,000	1.7

ICD – 10 – PCS Procedure Codes for Inpatient Hospital Billing

Potential ICD-10-Procedure Code	Description
Transcatheter Aortic Valve Replacement (TAVR)	
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 physician 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 CT01737528)

* Medicare will return all other claims as unprocessable

Transcatheter Mitral Valve-in-Valve (TM-VIV)	
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

ICD – 10 – CM Diagnosis Codes for Inpatient Hospital Billing

Potential ICD-10-Diagnosis Code	Description
Aortic Stenosis	
I35.0	Nonrheumatic aortic (valve) stenosis
Bicuspid Valve	
Q23.0	Congenital stenosis of the aortic valve

ICD – 10 – CM Diagnosis Codes for Inpatient Hospital Billing Cont.

Potential ICD-10-Diagnosis Code	Description
Valve-in-Valve (failed aortic surgical or transcatheter bioprosthetic, failed mitral surgical bioprosthetic, or failed pulmonic surgical bioprosthetic)	
T82.222A	Displacement of biological heart valve graft, initial encounter (e.g. Previously placed valve was malpositioned or became displaced)
T82.857A	Stenosis of cardiac prosthetic devices, implants and grafts, initial encounter (e.g. Previously placed valve developed stenosis prematurely)
T82.223A	Leakage of biological heart valve graft, initial encounter (e.g. Previously placed valve developed regurgitation prematurely)
Z45.09	Encounter for adjustment and management of other cardiac device (e.g. Previously placed valve developed stenosis or regurgitation as an expected occurrence as it degenerates toward valve end-of-life)
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
Z87.74	Personal history of (corrected) congenital malformations of heart and circulatory system (e.g. Factors influencing health status and contact with health services)
Z98.89	Other specified postprocedural states (e.g. Factors influencing health status and contact with health services)

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.

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.

Additional information may be available at the Edwards Lifesciences Reimbursement Hotline: (303) 524-3854 or edwards@rpihotline.com

Disclaimer
Important – Please Note:

Reimbursement information provided by Edwards Lifesciences is gathered from third-party sources and is presented for informational purposes only. Edwards makes no representation, warranty or guarantee as to the timeliness, accuracy, or completeness of the information and such information is not, and should not be construed as reimbursement, coding or legal advice. Any and all references to reimbursement codes are provided as examples only and are not intended to be a recommendation or advice as to the appropriate code for a particular patient, diagnosis, product or procedure or a guarantee or promise of coverage or payment, nor does Edwards Lifesciences warranty that codes listed are appropriate in all related clinical scenarios. It is the responsibility of the provider to determine if coverage exists and what requirements are necessary for submitting a proper claim for reimbursement to a health plan or payer, including the appropriate code(s) for products provided or services rendered. Laws, regulations, and payer policies concerning reimbursement are complex and change frequently; service providers are responsible for all decisions relating to coding and reimbursement submissions. Medicare's Correct Coding Initiative and commercial payer policies are reviewed and updated several times each year. Accordingly, Edwards strongly recommends consultation with payers, reimbursement specialists and/or legal counsel regarding appropriate product or procedure codes, coverage, and reimbursement matters. All codes referenced herein are examples only and may not be all-inclusive. Laws, regulations, coverage policies and code sets (i.e., CPT, ICD-10, and HCPCS) are complex and updated frequently. Coding should be based on the medical record documentation and the code sets in effect at the time of service.

References

- Current Procedure Terminology (CPT) copyright 2020, 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.
- 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.
- Centers for Medicare & Medicaid Services. CY2021 Physician Fee Schedule (MPFS) Final Rule. Payments are effective January 1, 2021 through December 31, 2021.
- Centers for Medicare & Medicaid Services. FY2021 Inpatient Prospective Payment System (IPPS) Final Rule Correction Notice. Payments are effective October 1, 2020 through September 30, 2021.
- International Classification of Diseases, 10th Revision, Clinical Modification 2021 ICD-10-CM and PCS Expert for hospitals, volume 1,2, and 3.

Important Safety Information

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

Indications: The Edwards SAPIEN 3 and SAPIEN 3 Ultra 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 and SAPIEN 3 Ultra 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 or surgical bioprosthetic mitral valve 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.

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. 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 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 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, 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. Failure to use slow, controlled inflation and prescribed nominal inflation volumes may result in balloon rupture, and lead to patient death or serious injuries associated with difficulty retrieving the delivery system and surgical intervention.

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. 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 or abnormalities in the atrial septum preventing safe transseptal access. Special care must be exercised in mitral valve replacement if chordal preservation techniques were used in the primary implantation 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 any 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; bulky calcified aortic valve leaflets in close proximity to coronary ostia; a concomitant paravalvular leak where the failing bioprosthesis is not securely fixed in the native annulus or is not structurally intact (e.g., wireform frame fracture); 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. Ensure there is flow in Left Internal Mammary Artery (LIMA)/Right Internal Mammary Artery (RIMA) during procedure and monitor PA pressure in homolateral radial artery. Residual mean gradient may be higher in a "THV-in-failing bioprosthesis" 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 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 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 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 Axela Sheath

Indications: The Edwards Axela sheath is indicated for the introduction and removal of devices used with the Edwards SAPIEN 3 Ultra delivery system.

Contraindications: There are no known contraindications.

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.

Precautions: Caution should be used in vessels that have diameters less than 5.5 mm as it may preclude safe placement of the 14F Edwards Axela sheath. For subclavian/axillary vessels with the 29 mm Edwards SAPIEN 3 Ultra delivery system, caution should be used in vessels that have diameters less than 6.0 mm as it may preclude safe placement of the 14F Edwards Axela sheath. Use caution in tortuous or calcified vessels that would prevent safe entry of the sheath. Do not use the Edwards Axela sheath if the packaging sterile barriers and any components have been opened or damaged or the expiration date has elapsed. When inserting, manipulating or withdrawing a device through the sheath, always maintain sheath position. When puncturing, suturing or incising the tissue near the sheath, use caution to avoid damage to the sheath.

Potential Adverse Events: Complications associated with standard catheterization and use of angiography include, but are not limited to, injury including perforation or dissection of vessels, thrombosis and/or plaque dislodgement which may result in emboli formation, distal vessel obstruction, hemorrhage, infection, and/or death.

Edwards Crimper

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

Contraindications: There are no known contraindications.

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.

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 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. 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 postprocedure 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 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 are 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.

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • edwards.com

Edwards