## TRANSCATHETER AORTIC VALVE REPLACEMENT

This guide is intended to support diagnostic and procedural coding for Transcatheter Aortic Valve Replacement (TAVR) procedures.

### Facility Billing Guide

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<tbody>
<tr>
<td>TAVR</td>
<td>33361</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach</td>
<td>$1,414</td>
<td>$884</td>
<td>39.54</td>
</tr>
<tr>
<td></td>
<td>33362</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach</td>
<td>$1,546</td>
<td>$966</td>
<td>43.23</td>
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<tr>
<td></td>
<td>33363</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach</td>
<td>$1,623</td>
<td>$1,015</td>
<td>45.40</td>
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<tr>
<td></td>
<td>33364</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach</td>
<td>$1,683</td>
<td>$1,052</td>
<td>47.06</td>
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<tr>
<td></td>
<td>33365</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)</td>
<td>$1,852</td>
<td>$1,158</td>
<td>51.81</td>
</tr>
<tr>
<td></td>
<td>33366</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy)</td>
<td>$2,005</td>
<td>$1,253</td>
<td>56.08</td>
</tr>
<tr>
<td>Add-on Codes</td>
<td>33367+</td>
<td>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)</td>
<td>$650</td>
<td>NA</td>
<td>18.17</td>
</tr>
<tr>
<td></td>
<td>33368+</td>
<td>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)</td>
<td>$780</td>
<td>NA</td>
<td>21.82</td>
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<tr>
<td></td>
<td>33369+</td>
<td>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)</td>
<td>$1,030</td>
<td>NA</td>
<td>28.80</td>
</tr>
</tbody>
</table>

**Note:** As per the CMS’s NCD for TAVR, TAVR is a two-physician (IC & CS) procedure. Medicare payment for each physician is 62.5% of the established national average payment. Codes 33367, 33368 and 33369 are add-on codes which does not require modifier 62 hence each physician payment of 62.5% does not apply. Medicare will only pay TAVR physician claims with these CPT codes when billed with the 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) and ICD-9 secondary diagnosis code V70.7 (Examination of participant in clinical trial). Medicare requires reporting of the Clinical Trial (CT) number on the claim form. For example, the CT number for the TVT Registry is CT01735728 and the PARTNER II Trial is CT01314313. Medicare may return other claims as unprocessable. Codes 33361-33369 have a 0 day global period; Codes 33361, 33362, 33363, 33364, 33365, 33366, 33367, 33368 and 33369 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, 33362, 33363, 33364, 33365, 33366, 33367, 33368 and 33369 include all other catheterization[s], temporary pacing, intra procedural contrast injection[s], fluoroscopic radiological supervision and interpretation, and imaging guidance, which are not reported separately when performed to complete the aortic valve procedure.
Transcatheter Aortic Valve Replacement

**INCLUDES:**
- Access and Implantation of the aortic valve (33361-33366)
- Access sheath placement
- Advancement of valve delivery system
- Arteriotomy closure
- Balloon aortic valvuloplasty
- Cardiac or open arterial approach
- Deployment of valve
- Percutaneous access
- Temporary pacemaker
- Valve repositioning when necessary
- Radiology procedures:
  - Angiography during and after procedure
  - Assessment of access site for closure
  - Documentation of completion of the intervention
  -Guidances for valve placement
  - Supervision and interpretation

**EXCLUDES:**
- Percutaneous coronary interventional procedures
- Transvascular ventricular support (33967, 33970, 33973, 33975-33976, 33990-33993, 33999)
- Code also add-on codes for cardiopulmonary bypass, when appropriate (33367-33369)
- Code also cardiac catheterization services for purposes other than TAVR/TAVI
- Code also diagnostic coronary angiography at a different session from the interventional procedure
- Code also diagnostic coronary angiography at the same time as TAVR/TAVI when:
  - A previous study is available, but documentation states the patient’s condition has changed since the previous study, visualization of the anatomy/pathology is inadequate, or a change occurs during the procedure warranting additional evaluation of an area outside the current target area
  - No previous catheter-based coronary angiography study is available, and a full diagnostic study is performed, with the decision to perform the intervention based on that study
- 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
- Code also modifier 62 as all TAVI/TAVR procedures require the work of two physicians
- Do not report separately when included in the TAVR/TAVI service (93452-93453, 93458-93461, 933567)

**HOSPITAL INPATIENT DIAGNOSIS AND PROCEDURE CODING**

Medicare inpatient hospital reimbursement is based upon the Medicare Severity Diagnostic-Related Group (MS-DRG) classification system, which assigns MS-DRGs based on ICD-9-CM diagnosis and procedure codes. The following codes generally describe diagnosis and procedures associated with the use of the Edwards SAPIEN XT transcatheter heart valve.

<table>
<thead>
<tr>
<th>ICD-9-CM³ Diagnosis Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>424.1</td>
<td>Aortic valve disorders</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-9-CM³ Procedure Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>35.05⁴</td>
<td>Endovascular replacement of aortic valve</td>
</tr>
<tr>
<td>35.06⁴</td>
<td>Transapical replacement of aortic valve</td>
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</tbody>
</table>

Pursuant to the final rule for the FY 2015 hospital Inpatient Prospective Payment System (IPPS), CMS created new MS-DRGs for endovascular cardiac valve replacements, effective October 1, 2014.

<table>
<thead>
<tr>
<th>MS-DRG⁵</th>
<th>Description</th>
<th>FY 2015 Relative Weight</th>
<th>FY 2015 National Average Payment</th>
<th>FY 2015 Geometric Mean-LOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>266</td>
<td>Endovascular Cardiac Valve Replacement with MCC</td>
<td>8.9920</td>
<td>$52,742</td>
<td>8.4</td>
</tr>
<tr>
<td>267</td>
<td>Endovascular Cardiac Valve Replacement without MCC</td>
<td>6.7517</td>
<td>$39,602</td>
<td>5.0</td>
</tr>
</tbody>
</table>

**Note:** Medicare will only pay TAVR facility claims with these ICD-9-CM codes when billed with the ICD-9 secondary diagnosis code V70.7 (Examination of participant in clinical trial) and condition code 30 (qualifying clinical trial). Medicare will return all other claims as unprocessable.
Reimbursement Hotline: 1-800-471-9387

Disclaimer

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 the 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 and submit the appropriate claim for reimbursement. For more information about our commitments to legal matters, terms and conditions, and compliance issues, please visit our Edwards.com/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 consulting with payers, reimbursement specialists and/or legal counsel regarding appropriate product or procedure codes, coverage, and reimbursement matters.

Reference

1. Current Procedure Terminology (CPT) copyright 2014, American Medical Association (AMA). All rights reserved. CPT® is a trademarked register 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 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.


7. CMS Federal Register, Volume 79; Number 163, August 22, 2014/Rules and Regulations. The FY2015 Final Average standardized amount is $5865.48

8. CMS Federal Register, Volume 77; Number 222, November 16, 2012/Rules and Regulations

9. CMS Federal Register, Volume 79; Number 219, November 13, 2014/Rules and Regulations

IMPORTANT RISK INFORMATION

EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE WITH THE NOVAFLEX+ DELIVERY SYSTEM

Indications: The Edwards SAPIEN XT Transcatheter Heart Valve, model 9301TX, systems are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis (aortic valve area ≤ 0.8 cm² or aortic valve area index ≤ 0.6 cm²/m², a mean aortic valve gradient of > 40 mmHg, or a peak aortic-jet velocity of ≥ 4.0 m/s), and with native anatomy appropriate for the 23, 26, or 29 mm valve system, who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., Society of Thoracic Surgeons operative risk score ≥5% or at a ≥15% risk of mortality at 30 days).

Contraindications: The THV and delivery systems are contraindicated in patients who cannot tolerate an anticoagulant/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 is an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments. 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. Treatment of the THV with chemicals and/or sterilant may result in irreversible damage or annular rupture. Accelerated deterioration of the THV may occur in patients with an altered calcium metabolism. Prior to delivery, the THV must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. THV leaflets mishandled or damaged during any part of the procedure will require replacement of the THV. Caution should be exercised in implanting a THV in patients with clinically significant coronary artery disease. Patients with pre-existing mitral valve devices should be carefully assessed prior to implantation of the THV to ensure proper THV positioning and deployment. Do not use the THV if the tamper evident seal is broken, the storage solution does not completely cover the THV, the temperature indicator has been activated, the THV is damaged, or the expiration date has elapsed. Do not mishandle the NovaFlex+ 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. THV 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 THV.

Precautions: Long-term durability has not been established for the THV. Medical follow-up is advised to evaluate THV 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. Safety, effectiveness, and durability have not been established for valve-in-valve procedures. 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 unicusp or congenital bicuspid aortic valve, mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation > 3+), pre-existing prosthetic heart valve or 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, ticlodipine (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 “unfoiling” and tortuosity of the thoracic aorta, access characteristics that would preclude safe placement of 16F, 18F, or 20F Edwards Expandable Introducer Sheath Set, such as severe obstructive calcification, severe tortuosity or diameter less than 6 mm, 6.5 mm, or 7 mm, respectively, bulky calcified aortic valve leaflets in close proximity to coronary ostia.

Note: All codes listed are not necessarily applicable for all relevant clinical scenarios. It is the responsibility of the provider to determine if the code(s) provided herein are applicable to the patient's clinical presentation.
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, myocardium or valvular structures that may require intervention; pericardial effusion or cardiac tamponade; embolization including intracardiac, cerebral valve material or thrombus; infection including septicaemia and endocarditis; heart failure; myocardial infarction; renal insufficiency or renal failure; conduction system defect which may require a permanent pacemaker; arrhythmia; retroperitoneal bleed; AV fistula or pseudoaneurysm; reoperation; ischemia or nerve 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; fever. Additional potential risks associated with the use of the THV, 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; 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, non-emergent reoperation.

EDWARDS BALLOON CATHETER (9350BC20 and 9350BC23)

Indications: The Edwards balloon catheter is indicated for valvuloplasty of a stenotic aortic valve prior to implantation of the Edwards SAPIEN and SAPIEN XT transcatheter heart valves.

Contraindications: Other than standard risks associated with insertion of a cardiovascular catheter, there are no known contraindications for valvuloplasty. The patient’s medical condition could affect successful use of this catheter.

Warnings: The device is designed, intended, and distributed for single use only. Do not re sterilize 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 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.

Precautions: For special considerations associated with the use of this device prior to transcatheter heart valve implantation, refer to the bioprosthesis Instructions for Use (IFU). Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon. The device is not intended for post-dilatation of deployed transcatheter heart valves. While exposed within the body, device advancement and retrieval should not be done without the aid of fluoroscopy. Do not advance or retract the device unless the balloon is fully deflated under vacuum. The device is designed, intended, and distributed for single use only.

Potential Adverse Events: Complications associated with standard catheterization, balloon valvuloplasty, and the use of angiography include, but are not limited to, allergic reaction to anesthesia or to contrast media, injury including perforation or dissection of vessels, thrombus formation, plaque dislodgement and embolization that may result in myocardial infarction, stroke, distal peripheral occlusion and/or death, arrhythmia development, cardiac perforation, conduction system injury, hematoma, infundibular injury, annular tear or rupture and/or valve leaflet dehiscence, severe valve insufficiency, valve restenosis, valve damage, balloon rupture, balloon separation following balloon rupture, valvular tearing or trauma, thromboembolic events, and infection. Reference the Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System Instructions for Use, for a full list of potential adverse events.

EDWARDS BALLOON CATHETER (9350BC25)

Indications: The Edwards balloon catheter is indicated for valvuloplasty of a stenotic aortic valve prior to implantation of the Edwards SAPIEN XT transcatheter heart valve.

Contraindications: Other than standard risks associated with insertion of a cardiovascular catheter, there are no known contraindications for valvuloplasty. The patient’s medical condition could affect successful use of this catheter.

Warnings: The device is designed, intended, and distributed for single use only. Do not re sterilize 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 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.

Precautions: For special considerations associated with the use of this device prior to transcatheter heart valve implantation, refer to the bioprosthesis Instructions for Use. Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon. The device is not intended for post-dilatation of deployed transcatheter heart valves. While exposed within the body, device advancement and retrieval should not be done without the aid of fluoroscopy. Do not advance or retract the device unless the balloon is fully deflated under vacuum.

Potential Adverse Events: Complications associated with standard catheterization, balloon valvuloplasty, and the use of angiography include, but are not limited to, allergic reaction to anesthesia or to contrast media, injury including perforation or dissection of vessels, thrombus formation, plaque dislodgement and embolization that may result in myocardial infarction, stroke, distal peripheral occlusion and/or death, arrhythmia development, cardiac perforation, conduction system injury, hematoma, infundibular injury, annular tear or rupture and/or valve leaflet dehiscence, severe valve insufficiency, valve restenosis, valve damage, balloon rupture, balloon separation following balloon rupture, valvular tearing or trauma, thromboembolic events, and infection. Reference the Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System Instructions for Use for a full list of potential adverse events.

EDWARDS EXPANDABLE INTRODUCER SHEATH SET

Indications: The Edwards expandable introducer sheath is indicated for the introduction and removal of devices used with the Edwards SAPIEN XT Transcatheter Heart Valve.

Contraindications: This product is contraindicated for tortuous or calcified vessels that would prevent safe entry of the introducer and sheath. Warnings: The devices are designed, intended, and distributed for single use only. Do not re sterilize or reuse the devices. There is no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. The Edwards Expandable Introducer Sheath Set must be used with a compatible 0.035” guidewire.

Precautions: Do not use the introducer sheath set if the packaging sterile barriers and any components have been opened or damaged. The Edwards Expandable Sheath temporarily enlarges to allow the passage of devices; ensure that the vasculature can accommodate the maximum diameter of the expanded sheath. When inserting, manipulating or withdrawing a device through the expandable 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, stroke, infection, and/or death.

EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE WITH THE ASCENDRA+ DELIVERY SYSTEM

Indications: The Edwards SAPIEN XT Transcatheter Heart Valve, model 9300TFX, systems are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis (aortic valve area ≤ 1.0 cm² or aortic valve area index ≤ 0.6 cm²/m²), a mean aortic valve gradient of ≥ 40 mmHg, or a peak aortic-jet velocity of ≥ 4.0 m/s], and with native anatomy appropriate for the 23, 26, or 29 mm valve system, who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., Society of Thoracic Surgeons operative risk ≥8% or at a ≥15% risk of mortality at 30 days).

Contraindications: The THV 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 is an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments. The devices are designed, intended, and distributed for single use only. Do not re sterilize or reuse the devices. There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. Incorrect sizing of the THV may lead to paravalvular leak, migration, embolization and/or annular rupture. Accelerated deterioration of the THV may occur.
in patients with an altered calcium metabolism. Prior to delivery, the THV must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. THV leaflets mishandled or damaged during any part of the procedure will require replacement of the THV. Caution should be exercised in implanting a THV in patients with clinically significant coronary artery disease. Patients with pre-existing mitral valve diseases should be carefully assessed prior to implantation of the THV to ensure proper THV positioning and deployment. Patients presenting with combination AV low flow, low gradient should undergo additional evaluation to establish the degree of aortic stenosis. Do not use the THV if the tamper evident seal is broken, the storage solution does not completely cover the THV, the temperature indicator has been activated, the THV is damaged, or the expiration date has elapsed. Do not mishandle the Ascenda+ 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. 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. THV recipients should be maintained on an antibiotic/platelet 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 THV.

Precautions: Long-term durability has not been established for the THV. Regular medical follow-up is advised to evaluate THV 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. Safety, effectiveness, and durability have not been established for valve-in-valve procedures. 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 or congenital bicuspid aortic valve, mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation > 3+), pre-existing existing heart valve or prosthesis 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 (<50,000/microliter) or history of bleeding diathesis or coagulopathy, hyporeninemic hypoaldosteronism, or any other obstruction (HOCM), echocardiographic evidence of intracardiac mass, thrombus, or vegetation, a known hypersensitivity to aspirin, heparin, ticlopidine (Ticlid™), or clopoidogrel (Plavix™), or sensitivity to contrast media, which cannot be adequately premedicated, excessive calcification of vessel at access site, bulky calcified aortic valve leaflets in close proximity to coronary ostia.

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 coronary dissection, vessel dissection or vasoconstriction, ventricular, myocardial infarction or cardiac tamponade; 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 affect the pacemaker; arrhythmia; retroperitoneal bleed; AV fistula or pseudoaneurysm; reoperation; ischemia or nerve 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; infection including septicemia; endocarditis; other valve related complications; valve dehiscence; severe valve insufficiency; valve restenosis; valve damage; balloon rupture; balloon separation following balloon rupture, valvular tearing or trauma, thromboembolic events, and infection. Reference the Edwards SAPIEN Transcatheter Heart Valve with the Ascenda Balloon Catheter, Edwards SAPIEN Transcatheter Heart Valve with the Ascenda+ delivery system, or the Edwards SAPIEN XT Transcatheter Heart Valve with the Ascenda+ Delivery System Instructions for Use for a full list of potential adverse events.

ASCENDRA BALLOON AORTIC VALVULOPLASTY CATHETER

Indications: The Ascenda Balloon Aortic Valvuloplasty Catheter is indicated for valvuloplasty of a stenotic aortic valve prior to implantation of the Edwards SAPIEN or Edwards SAPIEN XT Transcatheter Heart Valve.

Contraindications: Other than standard risks associated with insertion of a cardiovascular catheter, there are no known contraindications for valvuloplasty. The patient’s medical condition could affect successful use of this catheter.

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 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.

Precautions: For special considerations associated with the use of this device prior to transcatheter heart valve (THV) implantation, refer to the THV instructions for use (IFU). This catheter has not been tested with any transcatheter valve other than the Edwards SAPIEN and Edwards SAPIEN XT transcatheer heart valve. Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon. The device is not intended for post-dilation of deployed transcatheter heart valves. While exposed within the body, device advancement and retrieval should not be done without the aid of fluoroscopy. Do not advance or retract the device unless the balloon is fully deflated under vacuum.

Potential Adverse Events: Complications associated with standard catheterization, balloon valvuloplasty, and the use of angiography include, but are not limited to, allergic reaction to anesthesia or to contrast media, thrombus formation, plaque dislodgement which may result in myocardial infarction, arrhythmia, stroke, and/or death. Other adverse events. There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Do not mishandle the device 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. Should not be used in patients with left ventricular aneurysm. The Ascenda+ Introducer Sheath Set must be used with a 0.035” guidewire.

Precautions: No known precautions.

Potential Adverse Events: Complications associated with cardiac surgical intervention and use of angiography include, but are not limited to, allergic reaction to anesthesia or to contrast media, injury including myocardial injury, thrombus formation, and plaque dislodgement which may result in myocardial infarction, arrhythmia, stroke, and/or death. Reference the Edwards SAPIEN XT Transcatheter Heart Valve with the Ascenda+ Delivery System Instructions for Use for a full list of potential adverse events.

EDWARDS CRIMPER

Indications: The Edwards Crimper is indicated for use in preparing the Edwards SAPIEN XT Transcatheter Heart Valve for implantation.
Contraindications: 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 this device prior to THV implantation, refer to the SAPIEN XT Transcatheter Heart Valve Instructions for Use.

Potential Adverse Events: No known potential adverse events.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.