See the Difference
Get a quick look at the treatment options to help your patient better understand them.

<table>
<thead>
<tr>
<th>SAVR</th>
<th>OR</th>
<th>TAVR</th>
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<tbody>
<tr>
<td>Available for all surgical risk patients (except prohibitive risk)¹</td>
<td></td>
<td>Available for intermediate- or greater-risk surgical patients¹</td>
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<tr>
<td>More invasive procedure²</td>
<td></td>
<td>Less invasive procedure²</td>
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<tr>
<td>Requires sternotomy (causing post-sternotomy pain syndrome lasting many years in some patients)²</td>
<td></td>
<td>Does not require sternotomy²</td>
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<tr>
<td>Requires stopping the heart and connecting the patient to a blood-pumping machine²</td>
<td></td>
<td>Does not require stopping the heart²</td>
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<tr>
<td>On average lasts approximately <strong>4 hours</strong>*</td>
<td></td>
<td>On average lasts approximately <strong>1.5 hours</strong>*</td>
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<tr>
<td>Average length of hospital stay is <strong>11.9 days</strong>*</td>
<td></td>
<td>Average length of hospital stay is <strong>5.5 days</strong>*</td>
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</tbody>
</table>

*Go to newheartvalve.com and learn more about TAVR, the less invasive treatment option.*

*The PARTNER II Trial intermediate-risk cohort unadjusted clinical event rates, AT population.

**References:**
2. SAPIEN 3 Patient Brochure for Intermediate or Greater Risk Patients; DOC-0041194D.

Please see Important Safety Information on the following pages.
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System and Accessories

Indications: The Edwards SAPIEN 3 Ultra transcatheter heart valve system and accessories are 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 at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 3% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator); and are also indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic or 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 STS risk score and other clinical comorbidities unmeasured by the STS risk calculator).

Contraindications: The valve 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 stroke risk 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 may occur 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, titanium, molybdenum, 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.

Precautions: Safety, effectiveness, and durability have not been established for THV-in-THV procedures. 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 Safety Data Sheet available from Edwards Lifesciences. To maintain proper valve leaflet coaptation, do not overinflate the delivery 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 Ocluder 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 unicusp aortic valve; mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation > 3+); 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 x 10^9/µL), 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 (hyperrcate 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; access characteristics that would preclude safe placement of the Edwards Axela sheath, such as severe obstructive calcification or severe tortuosity; excessive calcification at access site; 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., wireframe frame fracture); or a partially detached leaflet of the failing bioprosthesis that in the aortic position may obstruct a coronary ostium. 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 used 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, venticule, atrium, septum, myocardium, or valvular structures that may require intervention; pericardial effusion 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 require a permanent pacemaker; arrhythmia; retroperitoneal bleed; arteriovenous (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; and fever. Additional potential risks associated with the use of the valve, delivery system, and/or accessories include: cardiac arrest; cardiogenic shock; hypotension; anemia; abnormal lab values of the storage solution or rinsing solution; pericardial effusion 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 require a permanent pacemaker; arrhythmia; retroperitoneal bleed; arteriovenous (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; and fever. Additional potential risks associated with the use of the valve, delivery system, and/or accessories include: cardiac arrest; cardiogenic shock; hypotension; anemia; abnormal lab values of the storage solution or rinsing solution; pericardial effusion 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 require a permanent pacemaker; arrhythmia; retroperitoneal bleed; arteriovenous (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; and fever. Additional potential risks associated with the use of the valve, delivery system, and/or accessories include: cardiac arrest; cardiogenic shock; hypotension; anemia; abnormal lab values of the storage solution or rinsing solution; pericardial effusion 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 require a permanent pacemaker; arrhythmia; retroperitoneal bleed; arteriovenous (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; and fever.
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; injury to the mitral valve; device explants; mediastinitis; mediastinal bleeding; 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 exercised when sizing the native annulus or surgical valve; implanting a valve that is too small may lead to paravalvular leak, migration or embolization, whereas implanting a valve that is too large may lead to residual gradient (patient-prosthesis mismatch) or annular rupture. Accelerated deterioration of the valve may occur in patients with an altered calcium metabolism. Prior to delivery, the valve must remain hydrated at all times and cannot be exolved 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 mitral valve devices 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. 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-plexed 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 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 contact, 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 transcatheter valve in transcatheter valve replacement 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 prosthetic ring mismatch, severe mitral annular calcification (MAC), severe (> 3+) mitral insufficiency, or Gorlin syndrome, blood dyscrasias defined as: leukopenia (WBC < 3000 cells/μL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 150,000 cells/μL), or history of bleeding diathesis (coagulopathy, hemorrhagic cardiomyopathy with or without obstruction (HOCM)) and/or 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 or thoracic aortic aneurysm defined as maximal luminal diameter 5 cm or greater; marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick 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-plexed 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 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 contact, 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 transcatheter valve in transcatheter valve replacement 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 prosthetic ring mismatch, severe mitral annular calcification (MAC), severe (> 3+) mitral insufficiency, or Gorlin syndrome, blood dyscrasias defined as: leukopenia (WBC < 3000 cells/μL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 150,000 cells/μL), or history of bleeding diathesis (coagulopathy, hemorrhagic cardiomyopathy with or without obstruction (HOCM)) and/or 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 or thoracic aortic aneurysm defined as maximal luminal diameter 5 cm or greater; marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick 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-plexed 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 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 contact, 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 transcatheter valve in transcatheter valve replacement 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 prosthetic ring mismatch, severe mitral annular calcification (MAC), severe (> 3+) mitral insufficiency, or Gorlin syndrome, blood dyscrasias defined as: leukopenia (WBC < 3000 cells/μL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 150,000 cells/μL), or history of bleeding diathesis (coagulopathy, hemorrhagic cardiomyopathy with or without obstruction (HOCM)) and/or 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 or thoracic aortic aneurysm defined as maximal luminal diameter 5 cm or greater; marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick 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-plexed 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 solutions, or to the valve.
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 surgical bioprosthetic aortic 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 internal orifice 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 neurolgia, and fatigue; paraplegia; femoral artery occlusion; non-union; infection; hemolysis; hemodynamic shock; bioprosthetic valve thrombosis; transfusion or intervention; cardiovascular injury including perforation or dissection of vessels, ventricle, myocardium or valvaral structures that may require intervention; pericardial effusion or cardiac tamponade; embolization including air; calcific valve material or thrombus; infection including sepsisemia 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; 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 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; valve thrombosis requiring intervention; valve thrombosis; device embolization; device migration or malposition requiring intervention; valve deployment in unintended location; valve stenosis; structural valve deterioration; noninfectious valve leakage, leaflet tear/tearing free edge, leaflet perforation; suture leaflet retraction, suture leaflet thrombosis; aortic root dilatation; aortic root regurgitation; thickening, stenosis; device degeneration; paravalvular or transvalvular leak; valve regurgitation; hemolysis; device exposure; restructural dysfunction; mechanical failure of delivery system, and/or accessories, non-emergent reoperation.

Edwards Expandable Intravascular Sheath Set

Indications: This product is contraindicated for tortuous or calcified vessels that would prevent safe entry of the introducer and sheath.

Contraindications: The Edwards expandable introducer sheath is intended for use in patients with symptomatic aortic valve disease due to severe native aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be at intermediate or higher risk for open surgical therapy (i.e., predicted risk of surgical mortality > 5% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator). The Edwards SAPIEN XT transcatheter heart valve and accessories are also indicated for patients with symptomatic heart disease due to failure (stenosis, insufficient, or combined) of a surgical/aortic 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., STS operative risk score ≥88% or a ≥15% risk of mortality at 30 days).

Contraindications: The devices are designed, intended, and distributed for single use only. Do not resterilize 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. Do not use the Edwards Expandable Sheath temporarily enlarges to allow the passage of devices; ensure that the valveucture 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, puncture through the tissue near the sheath’s common opening 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 death.

Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System

Indications: The Edwards SAPIEN XT transcatheter heart valve, model 9300T, and accessories are indicated for relief of aortic stenosis in patients with symptomatic aortic valve disease due to擅长 native aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be at intermediate or higher risk for open surgical therapy (i.e., predicted risk of surgical mortality > 5% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator). The Edwards SAPIEN XT transcatheter heart valve and accessories are also indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical/aortic 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., STS operative risk score ≥88% or a ≥15% risk of mortality at 30 days).

Contraindications: The devices are designed, intended, and distributed for single use only. Do not resterilize 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. Do not use the Edwards Expandable Sheath temporarily enlarges to allow the passage of devices; ensure that the valveucture 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, puncture through the tissue near the sheath’s common opening 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 death.

Edwards Expandable Intravascular 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 resterilize 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. Do not use the Edwards Expandable Sheath temporarily enlarges to allow the passage of devices; ensure that the valveucture 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, puncture through the tissue near the sheath’s common opening 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 death.

Edwards Expandable Intravascular 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 resterilize 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. Do not use the Edwards Expandable Sheath temporarily enlarges to allow the passage of devices; ensure that the valveucture 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, puncture through the tissue near the sheath’s common opening 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 death.
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 surgical bioprosthetic aortic 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 an accurate determination of the internal orifice 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, myocardium or valvular structures that may require intervention; pericardial effusion 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 require a permanent pacemaker; arrhythmia; retroperitoneal bleed; arteriovenous (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 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; 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.

**Ascendra+ Introducer Sheath Set**

**Indications:** The Ascendra+ introducer sheath set is indicated for the introduction and removal of devices used with the Edwards SAPIEN XT transcatheter heart valve.

**Contraindications:** 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. 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 Ascendra+ 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 Ascendra+ 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 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. 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 valve implantation, refer to the Edwards SAPIEN XT transcatheter heart valve Instructions for Use.

**Potential Adverse Events:** No known potential adverse events.

**Caution:** Federal (United States) law restricts this device to sale by or on the order of a physician.