Symptoms of severe aortic stenosis include: dyspnea or decreased exercise tolerance, heart failure, angina, syncope and presyncope.

Patients with severe aortic stenosis typically have an aortic valve area ≤ 1.0 cm².

<table>
<thead>
<tr>
<th>Stage</th>
<th>Definition</th>
<th>Valve Hemodynamics</th>
<th>Hemodynamic Consequences</th>
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</thead>
<tbody>
<tr>
<td>D1</td>
<td>High-gradient</td>
<td>Aortic jet velocity ≥ 4m/s or mean gradient ≥ 40 mmHg Or aortic valve area index ≤ 0.6 cm²/m²</td>
<td>Left ventricular diastolic dysfunction Left ventricular hypertrophy Pulmonary hypertension may be present</td>
</tr>
<tr>
<td>D2</td>
<td>Low-flow/low-gradient with reduced left ventricular ejection fraction</td>
<td>Resting aortic jet velocity &lt; 4m/s or mean gradient &lt; 40 mmHg Dobutamine stress echocardiography shows aortic valve area ≤ 1.0 cm² with aortic jet velocity ≥ 4m/s at any flow rate</td>
<td>Left ventricular diastolic dysfunction Left ventricular hypertrophy Left ventricular ejection fraction &lt; 50%</td>
</tr>
<tr>
<td>D3</td>
<td>Low-gradient with normal left ventricular ejection fraction or paradoxical low-flow</td>
<td>Aortic jet velocity &lt; 4m/s or mean gradient &lt; 40 mmHg Stroke volume index &lt; 35 mL/m² measured when patient is normotensive (systolic blood pressure &lt; 140 mmHg)</td>
<td>Increased left ventricular relative wall thickness Small left ventricular chamber with low stroke volume Restrictive diastolic filling Left ventricular ejection fraction ≥ 50%</td>
</tr>
</tbody>
</table>

- A Heart Valve Team consisting of an integrated, multidisciplinary group of healthcare professionals with expertise in heart valve disease should collaborate to provide optimal patient care.

- TAVR is a reasonable alternative to surgical aortic valve replacement in patients with symptomatic severe aortic stenosis who are at high risk for surgery.

The TAVR procedure can be performed via multiple delivery approaches, including:

- Transfemoral
- Transapical
- Transaortic
EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE WITH THE NOVAFLEX+ 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. Patients are judged at high or greater risk for open surgical therapy (i.e., Society of Thoracic Surgeons operative risk score ≥8% or at ≥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. 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 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, magnesium, silver, 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 judged 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 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 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, 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 calcium and surface irregularities) of the abdominal or thoracic aorta, severe (“unfooled”) 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.

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 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; reperfusion; 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 devices; 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 repair.

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 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 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.

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, death, peripheral embolization, conduction system injury, hematoma, intubulum 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 Transcatheter Heart Valve with RetroFlex 3 Delivery System, or 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 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 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, infundibulum 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 INTRODUCTOR 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. 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 embolism 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 9300TX, systems are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native aortic stenosis (mean gradient ≥ 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 ≥8% or at a ≥15% risk of mortality at 30 days).

Contraindications: The THV and delivery system 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 resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. Incorrect sizing of the 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 devices 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 Ascendra+ 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 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. 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 overinflated 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. Patients with pre-existing aortic valve prosthesis have not been established for patients with the following characteristics/indications: 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 mitral insufficiency, or Gorlin syndrome, blood dyscrasias defined as: leukenemia (WBC < 3000 cells/mL), acute anemia (Hb < 9 g/dL), thrombocyopenia (platelet count <50,000 cells/mL) or history of bleeding or anticoagulation therapy with heparin or warfarin, a known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid™), or clopidogrel (Plavix™), or sensitivity to contrast media, which cannot be adequately premedicated, excessive hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid™), or clopidogrel (Plavix™), or sensitivity to contrast media, which cannot be adequately premedicated, excessive hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid™), or clopidogrel (Plavix™), or sensitivity to contrast media, which cannot be adequately premedicated.

**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 neurosensory 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 sepsisca 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; hemoptoma; 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; coronary artery or 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, 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 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 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 re-use 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 transcatheter 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 and embolization which may result in myocardial infarction, stroke, distal peripheral occlusion and/or death, arrhythmia development, cardiac perforation, conduction system injury, hematoma, infundibulum 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 Transcatheter Heart Valve with the Ascendra Balloon Catheter, Edwards SAPIEN Transcatheter Heart Valve with the Ascendra 3 Delivery System, or the Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System Instructions for Use for a full list of potential adverse events.

ASCENDRA+ INTRODUCER SHEATH SET

Indications: The Ascenda+ 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 re-use 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 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 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 device is designed, intended, and distributed for single use only. Do not resterilize or re-use 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 transcatheter heart valve (THV) implantation, refer to the SAPIEN XT Transcatheter Heart Valve Instructions for Use.

Potential Adverse Events: No known potential adverse events.

References

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.


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