**TAVR Patient Screening Fact Sheet**

**An Overview of Who May Be a TAVR Candidate**

Per the ACC/AHA guidelines, echocardiography is the gold standard for diagnosing patients with aortic stenosis:

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Mild</th>
<th>Moderate (cm²)</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valve area</td>
<td>&gt; 1.5</td>
<td>1.0 - 1.5</td>
<td>&lt; 1.0</td>
</tr>
<tr>
<td>Mean gradient (mmHg)</td>
<td>&lt; 25</td>
<td>25 - 40</td>
<td>&gt; 40</td>
</tr>
<tr>
<td>Jet velocity (m/s)</td>
<td>&lt; 3.0</td>
<td>3.0 - 4.0</td>
<td>&gt; 4.0</td>
</tr>
</tbody>
</table>

Severe aortic stenosis is defined as:
Valve area < 1.0 cm² AND Mean gradient > 40 mmHg OR Jet velocity > 4.0 m/s

Determining patients who are candidates for transcatheter aortic valve replacement (TAVR):

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Inoperable Patients</th>
<th>High-Risk Patients</th>
<th>Low to Moderate Risk Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVR</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Open-Heart Surgery (AVR)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Minimal Incision Surgery (MIVS)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

The Edwards SAPIEN transcatheter heart valve may be delivered through several different approaches, including:

- **Transfemoral**
- **Transapical**
- **Transaortic**

The Edwards SAPIEN transcatheter heart valve Indication:
The Edwards SAPIEN transcatheter heart valve, model 9000TFX, sizes 23 mm and 26 mm, is indicated for patients with severe symptomatic calcified native aortic valve stenosis without severe aortic insufficiency and with ejection fraction >20% who have been examined by a heart team including an experienced cardiac surgeon and a cardiologist and found to either be: 1) inoperable and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis; or 2) be operative candidates for aortic valve replacement but who have a Society of Thoracic Surgeons predicted operative risk score ≥ 8% or are judged by the heart team to be at a ≥ 15% risk of mortality for surgical aortic valve replacement.

Visit [NewHeartValve.com](http://NewHeartValve.com) to find a TAVR hospital near you

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*Lester, SJ, Heilbron, B, et al. The Natural History and Rate of Progression of Aortic Stenosis. Chest 1998; 113:1109-1114*
**EDWARDS SAPIEN TRANSCATHETER HEART VALVE WITH THE RETROFLEX 3 DELIVERY SYSTEM**

**Indications**: The Edwards SAPIEN transcatheter heart valve, model 90001FX, sizes 23 mm and 26 mm, is indicated for patients with severe symptomatic aortic stenosis with an aortic valve area (<1.0 cm²) and an aortic gradient >40 mm Hg at rest, who are at prohibitive risk for an open surgical procedure. The device is intended for transcatheter aortic valve replacement (TAVR) in patients who meet Edwards Lifesciences’ definition of severe symptomatic aortic stenosis. The aortic valve area is defined as the area of the valve orifice which is typically measured by echocardiogram; significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater, marked tortuosity (hypercute 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 “unloading” and “torquility” of the thoracic aorta; access site characteristics that would preclude safe placement of 22F or 24F introducer sheath such as severe obstructive calcification, severe tortuosity or diameter of less than 7 mm; and bulky calcified aortic valve leaflets in close proximity to coronary ostia.

**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, non-pyrogenicity, 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. Use of excess 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 chromium, nickel, molybdenum, manganese, copper, 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.

**Precautions**: Long-Term durability has not been established for the bioprosthesis. Regular medical follow-up is advised to evaluate bioprosthesis 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 material safety data sheet available from Edwards Lifesciences. To maintain proper valve leaflet function, ensure proper balloon positioning and balloon deflation. Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon. The device is not intended for repetitive bioprosthetic 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 rupture, thromboembolic events, and infection. Reference the Edwards SAPIEN bioprosthetic 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
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 tears or trauma, thromboembolic events, and infection. Reference the Edwards SAPIEN transcatheter heart valve with the RetroFlex 3 delivery system instructions for use for a full list of potential adverse events.

EDWARDS SAPIEN TRANSCATHETER HEART VALVE WITH THE ASCENDA 3 DELIVERY SYSTEM

Indications: The Edwards SAPIEN transcatheter heart valve model 9000TFX, sizes 23 mm and 26 mm, is indicated for patients with severe symptomatic calcified native aortic valve stenosis without severe aortic valve insufficiency and with ejection fraction > 20% who have been examined by a heart team including an interventional cardiologist and a cardiac surgeon and have been determined to be candidates for transcatheter aortic valve replacement (TAVR). The procedure is intended to alleviate symptoms associated with chronic aortic stenosis and 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 stability, non-pyrogenicity, and functionality of the devices after reprocessing. Incorrect sizing of the bioprosthesis may lead to paravalvular leak, migration, embolization, and/or annular rupture. Accelerated deterioration of the bioprosthesis may occur in patients with an altered calcium metabolism. Bioprostheses must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Bioprosthesis leaflets mishandled or damaged during any part of the procedure will require replacement of the bioprosthesis. Caution should be exercised in implanting a bioprosthesis in patients with clinically significant coronary artery disease. Patients with pre-existing mitral valve devices should be carefully assessed prior to implantation of the bioprosthesis to ensure proper bioprosthesis positioning and docking. Patients presenting with combination AV low flow, low gradient should undergo additional evaluation to establish the degree of aortic stenosis. Do not use the bioprosthesis if the tamper evident seal is broken, the storage solution does not completely cover the bioprosthesis, the temperature indicator has been activated, or the bioprosthesis is damaged, or the expiration date has elapsed. Do not mishandle the Ascenda 3 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 in patients with hypersensitivities to iodine, contrast, benzyl alcohol, benzyl benzoate, thimerosal, silicone, and/or other components. 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. The safety and efficacy of the transapical procedure has only been evaluated in those patient populations where the transfemoral procedure delivery is not suitable.

Precautions: Long-term durability has not been established for the bioprosthesis. Regular medical follow-up is advised to evaluate bioprosthesis 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. Skin contact occurs in the event of contact with eyes, skin, mucous membranes, or wounds. The procedure should be conducted under fluoroscopic guidance. For more information about glutaraldehyde exposure, refer to 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. Bioprosthetic valve recipients should be maintained on anticoagulant and antiplatelet therapy (e.g. clopidogrel or ticlopidine [75 mg/ day]) for 6 months post procedure and aspirin (75-100 mg/day) for life, except when contraindicated, as determined by their physician. The safety of the bioprosthesis implantation has not been established in patients who have: pre-existing prosthetic heart valve or valve repair device in any position; severe ventricular dysfunction with ejection fraction < 20%; hypertrophic cardiomyopathy with or without obstruction (HOCM). 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 anulus; congenital unicuspid or congenital bicuspid aortic valve; mixed aortic valve disease (aortic stenosis and aortic regurgitation); predominant aortic regurgitation in any position; severe (> 3+) mitral insufficiency; Gorlin syndrome; blood dyscrasias defined as: leukopenia (WBC < 3000 mm3), acute anemia (Hb < 9 g/dl), thrombocytopenia (platelet count < 50,000 cells/mm3), 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; native aortic anulus size < 18 mm or > 25 mm as measured by echocardiogram; significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater; marked tortuosity (hyperacute bend), aortic arch aneurysma (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 aortic arch; 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 balloon catheterization for balloon valvuloplasty, the potential risk of acute or chronic pseudoaneurysm formation, vasospasm, distal migration of the prosthetic heart valve, pseudoaneurysm formation, dissection, thromboembolic events, and infection. Reference the Edwards SAPIEN transcatheter heart valve with the RetroFlex 3 delivery system instructions for use for a full list of potential adverse events.

ASCENDA 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 transcatheter heart valve.

Contraindications: Other than specific 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 stability, non-pyrogenicity, 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). This catheter has not been tested with any transcatheter valve other than the Edwards SAPIEN transcatheter heart valve. Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon. The device is 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
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 instructions for use for a full list of potential adverse events.

ASCENDRA 3 INTRODUCER SHEATH SET
Indications: The Ascenda 3 introducer sheath set is indicated for the introduction and removal of devices used with the Edwards SAPIEN 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 3 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 transcatheter heart valve with the Ascendra 3 delivery system instructions for use for a full list of potential adverse events.

CRIMPER
Indications: The crimper is indicated for use in preparing the Edwards SAPIEN 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 or use it 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 implantation, refer to the bioprosthesis instructions for use.
Potential Adverse Events: No known potential adverse events.

CAUTION: Federal 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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