TAVR Patient Screening Flow

1. Patient is diagnosed with symptomatic severe native calcific aortic stenosis and referred to the Heart Team for evaluation.

2. The aortic valvular complex is evaluated using echocardiography.

3. The aortic valvular complex and peripheral vasculature are evaluated using MDCT.
The aortic valvular complex and peripheral vasculature are evaluated using catheterization.

Patient is evaluated by the Heart Team and meets the indication for TAVR.

Appropriate access route for TAVR procedure is determined by the Heart Team.

The above is a suggested flow for the patient screening process, however, the order in which screening tests are conducted varies depending on the patient’s profile and should be at the discretion of the Heart Team.
This guide provides an overview of the screening process used by Heart Teams to evaluate patients for transcatheter aortic valve replacement (TAVR) with the Edwards SAPIEN XT transcatheter heart valve.

Please visit www.NewHeartValve.com/hcp to locate a Heart Team and TAVR center near you.
Patient is Diagnosed with Symptomatic Severe Native Calcific Aortic Stenosis

An Overview of the 2014 AHA/ACC Valvular Heart Disease Guidelines - Symptomatic Severe Aortic Stenosis

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>
</tr>
</thead>
<tbody>
<tr>
<td>D1</td>
<td>High-gradient</td>
<td>- Aortic jet velocity ≥ 4m/s or mean gradient ≥ 40 mmHg&lt;br&gt;- Or aortic valve area index ≤ 0.6 cm²/m²</td>
<td>- Left ventricular diastolic dysfunction&lt;br&gt;- Left ventricular hypertrophy&lt;br&gt;- 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&lt;br&gt;- 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&lt;br&gt;- Left ventricular hypertrophy&lt;br&gt;- 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&lt;br&gt;- 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&lt;br&gt;- Small left ventricular chamber with low stroke volume&lt;br&gt;- Restrictive diastolic filling&lt;br&gt;- Left ventricular ejection fraction ≥ 50%</td>
</tr>
</tbody>
</table>

After the onset of symptoms, patients with severe aortic stenosis have a survival rate as low as 50% at 2 years without aortic valve replacement.
After a patient is diagnosed with symptomatic severe native calcific aortic stenosis, patients will need various imaging tests to assess if they are appropriate candidates for the transcatheter heart valve and delivery method. Comprehensive imaging tests will assess: the aortic valvular complex, cardiac structures and function, aortic arch, and peripheral vessels.

Transthoracic Echocardiography (TTE) is generally the first approach in assessing the annulus size due to its non-invasiveness

- TTE underestimates the annulus size and is typically used to obtain an estimation of annulus size

Transesophageal Echocardiography (TEE) is used to confirm annulus size when TTE measurements are borderline or the image quality is poor

- TTE (A) should occur in a parasternal long-axis view
- TEE (B) should occur in a left ventricular long-axis view (~120°)
Transesophageal Echocardiography is used to evaluate the size of the aortic annulus

- When the annulus size is assessed by TEE:
  
  - Measurements are taken during systole at the plane of the hinge points of the native valve leaflets at the largest diameter
  
  - The long-axis plane is positioned between the left and non-coronary cusps and through the right coronary cusp
Gated Multi-Detector Computed Tomography (MDCT) is used to evaluate the size of the aortic annulus

- Annulus assessment via ECG-gated cardiac MDCT and 3D echocardiography allows the evaluation of the annulus in an orthogonal plane at the level of the basal ring.

- The annulus is a dynamic structure that changes shape during the cardiac cycle:
  - Largest during systole
  - Smaller and more ovoid during diastole

- It is critical to obtain accurate sizing measurements and it is recommended to use a systolic series obtained from MDCT
  - Patient is not moving during acquisition
  - ECG triggered or gated CT
  - Contrast-enhanced
  - Slice thickness of heart (less than) 1 mm
  - Dose modulation switched off or only used for diastole (drop in diastole increase in systole)
  - Reconstruct in 5-10% increments from 25% - 45% of the R-R interval which helps ensure the maximum area is determined
THV size recommendations are based on native valve annulus size, as measured by transesophageal echocardiography (TEE) or computed tomography (CT). Patient anatomical factors and multiple imaging modalities should be considered during THV size selection. Note: Risks associated with undersizing and oversizing should be considered.

<table>
<thead>
<tr>
<th>THV Size to Annulus Size*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>THV Size</strong></td>
</tr>
<tr>
<td>Native Valve Annulus Size (TEE)</td>
</tr>
<tr>
<td>Native Valve Annulus Size (CT) Area</td>
</tr>
<tr>
<td>Native Valve Annulus Size (CT) Area Derived Diameter</td>
</tr>
</tbody>
</table>

*THV size recommendations are based on native valve annulus size, as measured by transesophageal echocardiography (TEE) or computed tomography (CT). Patient anatomical factors and multiple imaging modalities should be considered during THV size selection. Note: Risks associated with undersizing and oversizing should be considered.
The Aortic Valvular Complex and Peripheral Vasculature are Evaluated Using MDCT

Gated MDCT is used to evaluate the aortic valvular complex:

- Location and extent of leaflet calcification is evaluated
- For **transapical** patients, preoperative chest CT may be helpful in determining the orientation of the apex to determine suitability for access
- For **transaortic** patients, preoperative chest CT may be helpful in determining the anatomical relationship of the sternum and ascending aorta
MDCT is used to evaluate the peripheral vasculature to determine patient appropriateness for the transfemoral procedure:

- Minimum lumen diameters should be measured along the length of the common femoral, external iliac and common iliac arteries
- Internal diameter measurements should not include calcium

<table>
<thead>
<tr>
<th>Edwards SAPIEN XT THV Size</th>
<th>23 mm</th>
<th>26 mm</th>
<th>29 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suggested minimum vessel size</td>
<td>6 mm</td>
<td>6.5 mm</td>
<td>7 mm</td>
</tr>
<tr>
<td>eSheath profile</td>
<td>16F</td>
<td>18F</td>
<td>20F</td>
</tr>
</tbody>
</table>

Note: For patients with renal failure, non-contrast CT or IVUS of the iliac may be used to evaluate the extent of calcification in the vessel and estimate vessel diameter
The Aortic Valvular Complex and Peripheral Vasculature are Evaluated Using Catheterization

The following may be evaluated using catheterization:

- Degree of calcification and tortuosity of the peripheral vasculature
- Qualitative assessment of angulation and degree of stenosis of the aortic arch and distance of the coronary ostia from the aortic annulus
Assessment of the coronary arteries to determine if revascularization is necessary
According to the National Coverage Determination Memo published by the Centers for Medicare and Medicaid Services (CMS), two cardiac surgeons must independently examine the patient face-to-face and evaluate the patient’s suitability for open aortic valve replacement surgery; both surgeons are required to document the rationale for their clinical judgement and make this rationale available to the Heart Team.

**HIGH OR GREATER RISK PATIENTS:** who are judged by a Heart Team, including a cardiac surgeon, may be considered for TAVR if they have an STS operative risk score of ≥ 8% or are at a ≥ 15% risk of mortality at 30 days. See page 18 and 19 for indications and Important Risk Information.

In addition, some patients may have a low STS score but present with co-existing conditions that prevent the patient from being a suitable candidate for surgery. These conditions include:

- Extensively calcified (porcelain) aorta
- Chest wall deformity
- Oxygen-dependent respiratory insufficiency
- Frailty
Appropriate Access Route for Aortic TAVR Procedure is Determined

- Transfemoral Approach
- Transapical Approach
- Transaortic Approach
### Appropriate Access Route for Aortic TAVR
Procedure is Determined

<table>
<thead>
<tr>
<th>Anatomy</th>
<th>Transfemoral Approach Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter of iliac and femoral arteries</td>
<td>- Femoral and iliac arteries ≥ 6 mm for 23 mm valve, ≥ 6.5 mm for 26 mm valve and ≥ 7 mm for 29 mm valve</td>
</tr>
<tr>
<td>Calcification of iliac and femoral arteries</td>
<td>- No significant calcification of the femoral or iliac arteries</td>
</tr>
<tr>
<td></td>
<td>- No significant calcification of the aortic bifurcation</td>
</tr>
<tr>
<td>Tortuosity of iliac and femoral arteries</td>
<td>- No severe tortuosity of the arterial pathway from the femoral artery to the aortic bifurcation</td>
</tr>
<tr>
<td>Ventricle</td>
<td>- Severe LV dysfunction</td>
</tr>
<tr>
<td></td>
<td>- Hostile apex</td>
</tr>
<tr>
<td></td>
<td>- LV aneurysm</td>
</tr>
<tr>
<td></td>
<td>- Dyskinetic ventricle</td>
</tr>
<tr>
<td></td>
<td>- Quality of the tissue – frail, immunosuppressed patients</td>
</tr>
<tr>
<td></td>
<td>- Myocardial injury</td>
</tr>
<tr>
<td></td>
<td>- Severe COPD</td>
</tr>
<tr>
<td>Aorta</td>
<td>- No significant aortic disease, including no aneurysm, no presence of severe tortuosity and/or narrowing</td>
</tr>
<tr>
<td></td>
<td>- No horizontal aortic root and vertical valve plane</td>
</tr>
<tr>
<td></td>
<td>- No acute aortic arch angulation</td>
</tr>
<tr>
<td></td>
<td>- No aortic arch atheroma</td>
</tr>
</tbody>
</table>
### Transapical Approach Recommended
- Femoral and/or iliac arteries < 6 mm for 23 mm valve, < 6.5 mm and for 26 mm valve, and < 7 mm for 29 mm valve
- Iliofemoral bypass
- Extensive calcification of the femoral and/or iliac arteries
- Extensive calcification of aortic bifurcation
- Severe tortuosity of the arterial pathway from the femoral artery to the aortic bifurcation
- Free from pericardial disease or dyskinetic or aneurysmal ventricular apex

### Transaortic Approach Recommended
- Femoral and/or iliac arteries < 6 mm for 23 mm valve, < 6.5 mm and for 26 mm valve, and < 7 mm for 29 mm valve
- Iliofemoral bypass
- Extensive calcification of the femoral and/or iliac arteries
- Extensive calcification of aortic bifurcation
- Severe tortuosity of the arterial pathway from the femoral artery to the aortic bifurcation
- Severe LV dysfunction
- Hostile apex
  - LV aneurysm
  - Dyskinetic ventricle
  - Quality of the tissue – frail, immunosuppressed patients
- Myocardial injury
- Severe COPD

- Adequate distance from puncture to aortic annular plane (5.0 cm for 23 mm valve, 5.5 cm for 26 mm valve and 6.0 cm for 29 mm valve)
- No significant aortic disease, including no aneurysm
- No aortic arch atheroma
- No excessive calcification of aorta at access site
Why recommend an Edwards transcatheter heart valve for your patient?

The Edwards SAPIEN transcatheter heart valve platform is designed to imitate surgical valves in design and outcomes. They are the most widely used transcatheter heart valves worldwide and consistently demonstrate clinical excellence in both trials and real-world experience.

- **Designed for Durability**
  Edwards transcatheter heart valves use proven tissue and leverage the manufacturing processes of our leading surgical heart valves which have over 20 years of durability data.

- **Low Incidence of Complications and Permanent Pacemakers**
  Low frame height minimizes the risk of coronary obstruction and conduction system interference. SAPIEN valves consistently demonstrate low rates of permanent pacemaker implantation.

- **Optimal Hemodynamic Performance**
  The balloon-expandable, high radial strength frame is designed to achieve circularity* at the annulus to maximize area and flow while promoting full expansion and apposition at the annulus to minimize aortic regurgitation.

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 score ≥ 8% or at a ≥ 15% risk of mortality at 30 days).

*Data on file at Edwards Lifesciences
The 23 mm, 26 mm, and 29 mm sizes of the Edwards SAPIEN XT valve are designed to treat an annulus size range of 18-27 mm on TEE and 20-29 mm on CT.
References


See accompanying Important Risk Information.

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

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EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE WITH THE NOVAFLEX+
DELIVERY SYSTEM
Indications: The Edwards SAPIEN XT Transcatheter Heart Valve, model 0002TTX, are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe aortic stenosis (mean aortic valve gradient ≥ 40 mmHg, or a peak aortic jet velocity of 4.0 m/s, and with native anatomy appropriate for the 23, 26, 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 (e.g., Society of Thoracic Surgeons operative risk score ≤ 40). The Edwards SAPIEN XT Transcatheter Heart Valve is not intended for use in patients with cardiac tamponade. The device should be used according to the manufacturer's instructions for use.

Contraindications: Prior to the use of the Edwards SAPIEN XT Transcatheter Heart Valve, the overall risk-benefit analysis should be determined. When considering aortic valve replacement, the potential risk of pacing lead perforation. There is an increased risk of stroke in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis. Patients with a percutaneous coronary intervention (PCI) procedure and a planned aortic valve procedure should be carefully assessed prior to implantation of the Edwards SAPIEN XT Transcatheter Heart Valve, as there is a risk of bleeding, and coronary flow obstruction/transvalvular flow disturbance; device thrombosis requiring rethrombolysis; myocardial infarction; stroke; distal peripheral occlusion and/or death, arrhythmia

Precautions: The Edwards SAPIEN XT Transcatheter Heart Valve is intended for use in patients with symptomatic heart disease due to severe aortic stenosis (mean aortic valve gradient ≥ 40 mmHg, or a peak aortic jet velocity of 4.0 m/s, and with native anatomy appropriate for the 23, 26, 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 (e.g., Society of Thoracic Surgeons operative risk score ≤ 40). The device should be used according to the manufacturer's instructions for use.

EDWARDS BALLOON CATHETER (9350BC20 and 9350BC23)
Indications: The Edwards balloon catheter is indicated for valvuloplasty of a stenotic aortic, mitral, or tricuspid valve. The Edwards balloon catheter is intended for use by a physician trained in the catheterization and balloon catheter procedures.

Contraindications: Other than standard risks associated with insertion of a cardiac catheter, there are no known contraindications for valvuloplasty. The patient's medical condition should be evaluated for any other contraindications.

Precautions: Special considerations associated with the use of the device prior to procedures that require heart valve implantation, include: Precautions for the use of the device are the same as for the balloon catheter. The device is not intended for post-dilation of deployed transcatheter heart valve. In patients with aortic valve regurgitation, if the valve is not fully deflated under vacuum.

EDWARDS BALLOON CATHETER (9300BC90 and 9300BC20)
Indications: The Edwards balloon catheter is indicated for valvuloplasty of a stenotic aortic valve. The Edwards balloon catheter is intended for use by a physician trained in the catheterization and balloon catheter procedures. The device is not intended for post-dilation of deployed transcatheter heart valve. In patients with aortic valve regurgitation, if the valve is not fully deflated under vacuum.

Warnings: The device is designed, intended, and distributed for single use. Do not resterilize or re-use the device. There are no data to support the safety, non-pyrogenicity, and sterility of the device when re-sterilized. The device is not intended for use in multiple patients. The balloon is fully deflated under vacuum.

Potential Adverse Events: Complications associated with standard catheterization, balloon valvuloplasty, and the use of angiography include: death; stroke/transient ischemic attack, clusters or neurological deficits; paralysis; permanent disability; respiratory insufficiency or respiratory failure; cardiovascular injury including myocardial infarction, stroke, peripheral occlusion and/or death, arrhythmia

EDWARDS INTRODUCTORY SHEET
Indications: The Edwards expandable introducer sheath is intended for the introduction and delivery of transcatheter heart valves. The Edwards expandable introducer sheath is intended for use in conjunction with the Edwards SAPIEN XT Transcatheter Heart Valve. The Edwards expandable introducer sheath is intended for use with the Edwards SAPIEN XT Transcatheter Heart Valve Data Sheet available from Edwards Lifesciences. To maintain proper valve leaflet function, it is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. The Edwards expandable introducer sheath has been evaluated in vitro in valve prosthesis. Safety and effectiveness has not been established for patients with the following native or native-like aortic conditions: ventricular sep- tation defects; coronary artery fistula; aortic arch hypoplasia; true aortic aneurysm defined as maximal luminal diameter 5 cm or greater; marked tortuosity (distal and proximal vascular access sites), ulcerated; or narrowing (especially with calcium and surface irregularities) of the aortic arch or coronary arteries. The Edwards expandable introducer sheath has characteristics that would preclude safe placement of 10F, 16F, or 18F Edwards Expandable Introducer Sheath in the thoracic aorta. The Edwards expandable introducer sheath is not recommended for use in the aorta in patients with an aortic di- mean aortic valve gradient of 0.6 cm2/m2, a mean aortic valve gradient of 0.4 cm2/m2, and with native anatomy appropriate for the 23, 26, 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 (e.g., Society of Thoracic Surgeons operative risk score ≤ 40). The device should be used according to the manufacturer's instructions for use.

Contraindications: Do not use the introducer sheath set if the packaging sterile barriers and any components are not sterile, have been opened or are damaged (e.g., kinked or stretched), the temperature indicator has been activated, the THV is damaged, or the expiration date has elapsed. Use of excessive contrast media may lead to renal dysfunction with ejection fraction < 20%, congenital unicuspid or congenital bicuspid aortic valve, retrosternal aortic valve (aortic valve stenosis and aortic regurgitation with poststenotic aortic regurgitation). 3- pre-existing prosthesis or prosthesis in any position, severe renal insufficiency (eGFR ≤ 30 mL/min/1.73 m2), severe aortic insufficiency, or Gorlin syndrome, blood dyscrasias defined as a leukocyte (RBCS - 3000, neutrophils ≤ 500 cells/mm3, platelets ≤ 50,000 cells/ mm3); history of bleeding defects or coagulopathy, hyperlipidemic cardiovascular disease with or without myocardial infarction, uncontrolled hypertension or anemia, unstable angina, or diabetes mellitus, severe peripheral vascular disease, severe renal insufficiency (creatinine level > 3 mg/dL), or dialysis, cardiac tamponade, hemorrhagic stroke, severe mitral regurgitation, pericardial effusion, coronary artery disease, congestive heart failure, symptomatic ischemia, or myocardial infarction.

Precautions: There are no data to support the safety, non-pyrogenicity, and sterility of the device when re-sterilized. The device is not intended for use in multiple patients. The balloon is fully deflated under vacuum.
EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE WITH THE ASCENDRA+

Contraindications:
- A THV in patients with clinically significant coronary artery disease. Patients with pre-
procedure will require replacement of the THV. Caution should be exercised in implanting 
a THV in patients with calcific valve disease or aortic insufficiency.

Warnings:
- Do not advance or retract the device unless the balloon is fully deflated under vacuum. 
body, device advancement and retrieval should not be done without the aid of fluoroscopy. 

Precautions:
- Use of angiography: death; stroke/transient ischemic attack, clusters or neurological 
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, and contrast media toxicity.

ASCENDRA+ INTRODUCER SHEATH SET

Indications:
- The THV and delivery systems are contraindicated in patients who
- ≤

No known contraindications. 

No known precautions.

No known potential adverse events.

EDWARDS CRIMPS

Precautions:
- 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.


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In Irvine, California 92614 USA

EDW A R D S  S A P I E N  X T  T R A N S C A T H E T E R  H E A R T  V A L V E  W I T H  T H E  A S C E N D R A +

Contraindications:
- The THV and delivery systems are contraindicated in patients who
- ASCE N D R A+

Other than standard risks associated with insertion of a cardiovascular 

Complications associated with cardiac surgical intervention

No known precautions.

Potential Adverse Events:

Potential Adverse Events:

Potential Adverse Events:

Blood, low shear gradient is needed to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. Do not mishandle the device. Do not re-

Warnings:
- The devices are designed, intended, and distributed for single use only. Do not reuse or 

Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ Delivery System for use in a follow-up of all potential adverse events. 

The THV and delivery systems are contraindicated in patients who

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EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE WITH THE ASCENDRA+

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