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

#### Stage: Symptomatic Severe Aortic Stenosis

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

#### 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.

#### Hemodynamic Consequences

- 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.

#### Visit NewHeartValve.com/hcp for additional resources.
Precautions: The Edwards balloon catheter is indicated for valvuloplasty of a stenotic aortic valve. Do not use for implantation of the Edwards SAPIEN XT transcatheter heart valve.

Contraindications: Other than standard risks associated with insertion of a catheter, there are no known contraindications for valvuloplasty. The patient’s medical condition must be carefully assessed to decide whether valvuloplasty is a viable option. Be aware that the potential risks associated with insertion of a balloon catheter include vascular injury or dissection, rupture, valvular tearing or trauma, thromboembolic events, and infection. Reference the Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System Instructions for Use for a full list of potential adverse events.

EDWARDS BALLOON CATHETER (9350BC20 and 9350BC23)

Indications: The Edwards balloon catheter is indicated for valvuloplasty of a stenotic aortic valve. Do not use for implantation of the Edwards SAPIEN XT transcatheter heart valve.

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painless, disfiguring, and long-lasting. THV recipients should be maintained on molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, opened or are damaged (e.g. kinked or stretched), or the expiration date has elapsed. Care solution does not completely cover the THV, the temperature indicator has been activated, AV low flow, low gradient should undergo additional evaluation to establish the degree of stenosis and/or aneurysm. A THV in patients with clinically significant coronary artery disease. Patients with pre-existing annular rupture. Accelerated deterioration of the THV may occur in patients with an altered coagulation state. Incorrect sizing of the THV may lead to paravalvular leak, migration, embolization and/or death. Do not resterilize or reuse the device. There is a risk of infection. The Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ System Instructions for Use for a full list of potential adverse events.

EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE WITH THE ASCENDRA+

Contraindications:

- The Ascendra Balloon Aortic Valvuloplasty Catheter is indicated for use in patients with symmetric, concentric, severe aortic stenosis who are not candidates for open surgical valve replacement (i.e., Society of Thoracic Surgeons operative risk score ≥ 8), or a peak aortic-jet velocity of ≤ 40 mmHg, or a mean aortic-jet velocity of ≤ 0.035" guidewire.
- There is an increased risk of stroke in patients with branched or complex coronary anatomy. There is an increased risk of stroke in patients with severe aortic insufficiency, severe mitral insufficiency, and/or abnormal right atrial pressure.
- There is an increased risk of stroke in patients with moderate to severe aortic insufficiency or severe mitral insufficiency.
- There is an increased risk of stroke in patients with a history of transient ischemic attack, stroke, or peripheral embolic events.
- There is an increased risk of stroke in patients with a history of atrial fibrillation, in particular those with a mechanical mitral or aortic valve, or those with a pacemaker or other electrophysiological device, or those with prior transient ischemic attack, stroke, or peripheral embolic events.
- There is an increased risk of stroke in patients with severe mitral regurgitation and/or left ventricular dysfunction with ejection fraction < 20%, congenital unicuspid or congenital bicuspid aortic valve, and/or aortic stenosis with an unfavorable left ventricular outflow tract obstruction.
- There is an increased risk of stroke in patients with severe aortic insufficiency, severe mitral insufficiency, and/or abnormal right atrial pressure.
- There is an increased risk of stroke in patients with a history of transient ischemic attack, stroke, or peripheral embolic events.
- There is an increased risk of stroke in patients with a history of atrial fibrillation, in particular those with a mechanical mitral or aortic valve, or those with prior transient ischemic attack, stroke, or peripheral embolic events.
- There is an increased risk of stroke in patients with severe mitral regurgitation and/or left ventricular dysfunction with ejection fraction < 20%, congenital unicuspid or congenital bicuspid aortic valve, and/or aortic stenosis with an unfavorable left ventricular outflow tract obstruction.

Potential Adverse Events:

- Potential adverse events associated with the general procedure including pain, fever, infection, pulmonary edema, hypotension, arrhythmia, pericardial effusion, myocardial infarction, pericarditis, stroke, and/or death.
- Potential adverse events associated with the use of this device include, but are not limited to: reaction to anesthesia or to contrast media, thrombus formation, platelet deposition and embolization, left atrial erosion/embolization, disseminated intravascular coagulation, embolization, and/or death.
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System Instructions for Use for a full list of potential adverse events.

EDWARDS CRIMPED INTRODUCTORY SHIELD SET

Contraindications:

- Contraindications: The Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ System Instructions for Use for a full list of potential adverse events.

Warnings:

- Warnings: The devices are designed, intended, and distributed for single use only. Do not reprocess or use the device if the packaging or any components are not sterile, have been opened or are damaged (e.g. kinked, stretched, or the expiration date has elapsed).

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.

No known potential adverse events.

Evaluative Studies: The Edwards Lifesciences Corporation. Edwards, Edwards Lifesciences, the stylized E logo, Ascendra, Ascendra 3, Edwards SAPIEN, Edwards SAPIEN XT transcatheter heart valve (THV), Edwards SAPIEN XT transcatheter heart valve. Use only appropriate balloon catheter and balloon inflation medium. Do not use air or gas medium to inflate the balloon. The device is not intended for use in conjunction with non-commercial and/or investigational THV. The THV is designed, intended, and distributed for single use only.

No known potential adverse events.

No known precautions.

System Instructions for Use for a full list of potential adverse events.

No known potential adverse events.

Irvine, California 92614 USA

Richards Edwards catheters CRMPD is indicated for use in preparing the Edwards SAPIEN XT Transcatheter Heart Valve for implantation.

The Edwards SAPIEN XT Transcatheter Heart Valve with the Ascendra+ System Instructions for Use for a full list of potential adverse events.

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