Low-risk patients deserve the lowest-risk procedure

1% death or disabling stroke at 1 year*

Only Edwards SAPIEN 3 TAVR is proven superior to surgery

*Compared to 2.9% death or disabling stroke at 1 year for surgery (P=0.03). PARTNER 3 Trial proved SAPIEN 3 TAVR is superior to surgery on the primary endpoint (all-cause death, all stroke, and rehospitalization) and multiple pre-specified secondary endpoints.
Low-risk patients are unique

They’re often younger, healthier and more active than your higher surgical risk patients. Because they have fewer comorbidities, their primary concern is their severe symptomatic aortic stenosis.

<table>
<thead>
<tr>
<th>Baseline Patient Characteristics</th>
<th>As Treated (AT) Populations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PARTNER 3 Trial Low-risk (n=950)</td>
</tr>
<tr>
<td>Mean Age</td>
<td>73</td>
</tr>
<tr>
<td>STS Score</td>
<td>1.9</td>
</tr>
<tr>
<td>NYHA Class III/IV</td>
<td>27.7%</td>
</tr>
<tr>
<td>KCCQ Score</td>
<td>70.2</td>
</tr>
<tr>
<td>CAD</td>
<td>27.8%</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>2.4%</td>
</tr>
<tr>
<td>COPD</td>
<td>5.6%</td>
</tr>
<tr>
<td>Permanent PPM</td>
<td>2.6%</td>
</tr>
</tbody>
</table>

References:


Superior to surgery for the outcomes that matter most*

PARTNER 3 Trial Clinical Events at 30 Days and 1 Year

<table>
<thead>
<tr>
<th></th>
<th>30 Days</th>
<th>1 Year</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SAPIEN 3 TAVR (n=496)</strong></td>
<td><strong>Surgery (n=454)</strong></td>
<td><strong>SAPIEN 3 TAVR (n=496)</strong></td>
<td><strong>Surgery (n=454)</strong></td>
</tr>
<tr>
<td>All-cause Death</td>
<td>0.4%</td>
<td>1.1%</td>
<td>1.0%</td>
</tr>
<tr>
<td>All Stroke</td>
<td>0.6%</td>
<td>2.4%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Rehospitalization†</td>
<td>3.4%</td>
<td>6.5%</td>
<td>7.3%</td>
</tr>
</tbody>
</table>

Low-risk patients expect to have a procedure that carries the lowest risk.

### Secondary Endpoints

<table>
<thead>
<tr>
<th>Event</th>
<th>SAPIEN 3 TAVR (n=496)</th>
<th>Surgery (n=454)</th>
<th>SAPIEN 3 TAVR (n=496)</th>
<th>Surgery (n=454)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rehospitalization Due to Heart Failure</td>
<td>0.2%</td>
<td>0.9%</td>
<td>1.4%</td>
<td>3.6%</td>
<td>P=0.029</td>
</tr>
<tr>
<td>Life-threatening/Disabling or Major Bleeding</td>
<td>3.6%</td>
<td>24.5%</td>
<td>7.7%</td>
<td>25.9%</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>Disabling Stroke</td>
<td>0.0%</td>
<td>0.4%</td>
<td>0.2%</td>
<td>0.9%</td>
<td>P=0.14</td>
</tr>
<tr>
<td>New-onset AFib</td>
<td>5.0%</td>
<td>39.5%</td>
<td>7.0%</td>
<td>40.9%</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>AKI</td>
<td>0.4%</td>
<td>1.8%</td>
<td>0.4%</td>
<td>1.8%</td>
<td>P=0.05</td>
</tr>
<tr>
<td>Moderate or Severe PVL</td>
<td>0.8%</td>
<td>0.0%</td>
<td>0.6%</td>
<td>0.5%</td>
<td>P=1.0</td>
</tr>
<tr>
<td>New PPM</td>
<td>6.5%</td>
<td>4.0%</td>
<td>7.3%</td>
<td>5.4%</td>
<td>P=0.21</td>
</tr>
</tbody>
</table>

*PARTNER 3 trial proved SAPIEN 3 TAVR is superior to surgery on the primary endpoint and multiple pre-specified secondary endpoints.

†Valve-related, procedure-related, or heart-failure-related.
Low-risk severe symptomatic aortic stenosis patients expect to resume their everyday lives rapidly post-procedure.

3 days of hospital stay with TAVR
compared to 7 days with surgery ($P<0.001$)

96% discharged home from hospital with TAVR
compared to 73.1% with surgery ($P<0.001$)

1.4% rehospitalization due to heart failure for TAVR patients at 1 year
compared to 3.6% with surgery ($P=0.029$)
Engineered for the future

SAPIEN 3 valves have low frame heights, which more easily facilitate future coronary access should your patient need to undergo a procedure post-TAVR.

<table>
<thead>
<tr>
<th>SAPIEN 3 Valve</th>
<th>20 mm</th>
<th>23 mm</th>
<th>26 mm</th>
<th>29 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frame Height (mm)</td>
<td>15.5</td>
<td>18.0</td>
<td>20.0</td>
<td>22.5</td>
</tr>
<tr>
<td>Commissure Height (mm)</td>
<td>13.1</td>
<td>15.3</td>
<td>16.9</td>
<td>19.1</td>
</tr>
<tr>
<td>Inner Skirt Height (mm)</td>
<td>7.9</td>
<td>9.3</td>
<td>10.2</td>
<td>11.6</td>
</tr>
</tbody>
</table>
For your severe symptomatic aortic stenosis patients

Give your low-risk patients the lowest-risk procedure with Edwards SAPIEN 3 TAVR

References:


The PARTNER 3 trial low-risk cohort 30-day and 1-year clinical event rates for TAVR with the SAPIEN 3 valve, AT population (n=950).


See enclosed Important Safety Information.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician.

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Edwards SAPIEN 3 THV System and Edwards SAPIEN 3 Ultra THV System

**Indications:** The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System 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 appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System are 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 co-morbidities unmeasured by the STS risk calculator).

**Contraindications:** The valves 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 risk of stroke 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 due to calcific degeneration may occur in children, adolescents, or young adults and 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, 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 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. Failure to use slow, controlled inflation and prescribed nominal inflation volumes may result in balloon rupture, and lead to patient death or serious injuries associated with difficulty retrieving the delivery system and surgical intervention.

**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 deployment balloon. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthesis 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 aortic annulus that could interfere with transseptal access. 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. Failure to use slow, controlled inflation and prescribed nominal inflation volumes may result in balloon rupture, and lead to patient death or serious injuries associated with difficulty retrieving the delivery system and surgical intervention.

**Important Safety Information**

**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; and other complications associated with open or transcatheter aortic valve replacement procedures. The Edwards SAPIEN 3 THV System and Edwards SAPIEN 3 Ultra THV System are contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.
There are no known contraindications.

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 is no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.

Precautions: Caution should be used in vessels that have diameters less than 5.5 mm or 6 mm as it may preclude safe placement of the 14F Edwards Axela sheath. For subclavian/axillary vessels with the 29 mm Edwards SAPIEN 3 Ultra delivery system, caution should be used in vessels that have diameters less than 6.0 mm as it may preclude safe placement of the 14F Edwards Axela sheath. Use caution in tortuous or calcified vessels that would prevent safe entry of the sheath. Do not use the Edwards Axela sheath if the packaging sterile barriers and any components have been opened or damaged or the expiration date has elapsed. When inserting, manipulating or withdrawing a device through the 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 emboli formation, distal vessel obstruction, hemorrhage, infection, and/or death.

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 is no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.

Precautions: Caution should be used in vessels that have diameters less than 5.5 mm as it may preclude safe placement of the 14F Edwards Axela sheath. For subclavian/axillary vessels with the 29 mm Edwards SAPIEN 3 Ultra delivery system, caution should be used in vessels that have diameters less than 6.0 mm as it may preclude safe placement of the 14F Edwards Axela sheath. Use caution in tortuous or calcified vessels that would prevent safe entry of the sheath. Do not use the Edwards Axela sheath if the packaging sterile barriers and any components have been opened or damaged or the expiration date has elapsed. When inserting, manipulating or withdrawing a device through the 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 emboli formation, distal vessel obstruction, hemorrhage, infection, and/or death.

Edwards eSheath

Indications: The Edwards eSheath introducer set is indicated for the introduction and removal of devices used with the Edwards SAPIEN 3 and the Edwards SAPIEN 3 Ultra transcatheter heart valves.

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 is no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. The Edwards eSheath introducer set must be used with a compatible 0.035” (0.89 mm) guidewire to prevent vessel injury.

Precautions: Caution should be used in vessels that have diameters less than 5.5 mm or 6 mm as it may preclude safe placement of the 14F and 16F Edwards eSheath introducer set respectively. Use caution in tortuous or calcified vessels that would prevent safe entry of the introducer set. Do not use the Edwards eSheath introducer set if the packaging sterile barriers and any components have been opened or damaged. When inserting, manipulating or withdrawing a device through the 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 emboli formation, distal vessel obstruction, hemorrhage, infection, and/or death.

Edwards Crimper

Indications: The Edwards crimper is indicated for use in preparing the Edwards SAPIEN 3 Ultra transcatheter heart valve and the Edwards SAPIEN 3 transcatheter heart valve for implantation.

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: For special considerations associated with the use of the Edwards crimper prior to THV implantation, refer to the THV Instructions for Use.

Potential Adverse Events: There are no known potential adverse events associated with the Edwards crimper.

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.