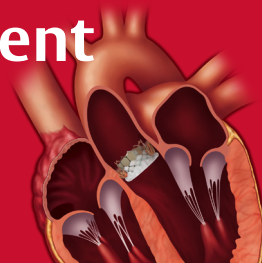


# Transcatheter Aortic Valve Replacement

Changing the Face of Treatment for Patients with Aortic Stenosis



Aortic stenosis (AS) is one of the most common and most serious valve disease problems<sup>1</sup>



With AS, the opening of the aortic heart valve narrows. As a result, the heart needs to work harder and may not pump enough oxygen-rich blood to the body.<sup>2</sup>

75 yo+



Approximately 2.5 million people in the U.S. 75 years or older suffer from AS.<sup>3</sup>

The symptoms of AS are commonly misunderstood by patients as 'normal' signs of aging

COMMON SYMPTOMS INCLUDE:<sup>4</sup>



- Fainting
- Breathlessness
- Chest pain, pressure or tightness
- Decline in activity level or reduced ability to do routine physical activities

Without treatment, severe symptomatic AS is life-threatening<sup>5</sup>

50% 20%

After the onset of symptoms, patients with severe AS have a survival rate as low as 50% at 2 years and 20% at 5 years without aortic valve replacement.<sup>6</sup>



Traditional treatment for this disease is open-heart surgery, which may require extensive hospital stays and recovery times.<sup>7</sup>

The need for another treatment option



There are people who have been diagnosed with severe, symptomatic AS and **who are at intermediate-risk for open-heart surgery**. Historically, such patients often refuse or are denied surgery.

## The SAPIEN Family of Valves in the U.S.

The Edwards SAPIEN 3 transcatheter aortic valve was approved in the U.S. in 2015 for the treatment of high or greater risk patients with severe, symptomatic AS. In 2016, the SAPIEN 3 valve was approved for an expanded indication to include patients at intermediate-risk of open-heart surgery. The first commercially available TAVR in the U.S., developed by Edwards, was approved in 2011.

2016



The SAPIEN family of valves has been used in the treatment of patients around the world.

## Patient Impact: TAVR Today



Short length of hospital stay.\*\*

\*\*The PARTNER II S3i trial, SAPIEN 3 Valve, unadjusted procedural factors (AT)

99%

The survival rate at 30 days for patients at intermediate-risk of open-heart surgery who received the SAPIEN 3 valve.\*\*\*

\*\*\*The PARTNER II trial intermediate-risk cohort 30-day unadjusted clinical event rates for TAVR with the SAPIEN 3 valve, AT population (n=1077)



Valves in the SAPIEN family are implanted in more patients worldwide than any other transcatheter heart valve.

Visit [SAPIEN3.com](http://SAPIEN3.com) for Important Safety Information.

**CAUTION: Federal (United States) law restricts these 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.**

The Edwards SAPIEN 3 transcatheter heart valve, model 9600TFX, and accessories 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 at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality  $\geq$  3% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

The TAVR procedure may involve general anesthesia and is associated with specific contraindications as well as adverse effects, including risks of death, major stroke, major vascular complications and life threatening bleeding event.

For more information about the benefits and risks of the SAPIEN 3 valve, visit [SAPIEN3.com](http://SAPIEN3.com).

1. [www.heart.org/HEARTORG/Conditions/More/HeartValveProblemsandDisease/Problem-Aortic-Valve-Stenosis\\_UCM\\_450437\\_Article.jsp#.Vt4DAX0rKM8](http://www.heart.org/HEARTORG/Conditions/More/HeartValveProblemsandDisease/Problem-Aortic-Valve-Stenosis_UCM_450437_Article.jsp#.Vt4DAX0rKM8) 2. [www.newheartvalve.com/what-is-aortic-stenosis](http://www.newheartvalve.com/what-is-aortic-stenosis) 3. U.S. Census Bureau, Population Division. June 2015 4. Das P. European Heart Journal. 2005;26:1309-1313 5. Lester SJ et al. CHEST 1998;113(4):1109-1114 6. Otto CM. Heart. 2000;84:211-218. 7. [www.heart.org/HEARTORG/Conditions/More/HeartValveProblemsandDisease/Newer-Heart-Valve-Surgery-Options\\_UCM\\_462302\\_Article.jsp#.Vt4GbX0rKM9](http://www.heart.org/HEARTORG/Conditions/More/HeartValveProblemsandDisease/Newer-Heart-Valve-Surgery-Options_UCM_462302_Article.jsp#.Vt4GbX0rKM9)

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