Transcatheter Heart Valves
Manufacturing Facts and Figures

At Edwards Lifesciences, we take pride in the level of care that goes into making each and every valve. Our valves are carefully hand-crafted by employees who share a passion for innovation and helping patients. Innovation is at the core of Edwards. It is this passion that allows us to produce the novel products and therapies used by patients around the world.

Transcatheter heart valves

Edwards’ leadership in transcatheter heart valve replacement includes a commitment to innovation, rigorous scientific study, extensive clinician training and education, and significant investment in new applications of the technology. Since introducing our first innovation more than 60 years ago, Edwards has continued to advance heart valve therapy and remains a global leader in this field.

On average, production of one Edwards transcatheter valve involves:

- Approximately 200 steps
- Approximately 140 employees
- Nearly 40 days of production
- Average 3 months to train 1 assembler
- More than 90 inspection points throughout
- Approximately 680 stitches

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Aortic stenosis (AS) is one of the most common and most serious valve disease problems.

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.

Approximately 2.5 million people in the U.S. 75 years or older suffer from AS.

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

Common Symptoms Include:
- Chest pain
- Rapid, fluttering heartbeat
- Feeling short of breath
- Feeling dizzy or light-headed even fainting

Severe aortic stenosis is life-threatening and treatment is critical.

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.

TAVR is the preferred therapy option for many AS patients.

Low-risk AS patients are often healthier and expect to resume their everyday lives rapidly post-procedure.

Edwards SAPIEN TAVR in the U.S.

The first commercially available TAVR in the U.S., developed by Edwards, was approved in 2011. The Edwards SAPIEN 3 valve was approved for patients with severe AS at high-risk of open-heart surgery in 2015, and received an expanded indication for intermediate-risk patients in 2016. In 2019, the SAPIEN 3 TAVR was approved for younger and healthier patients at low risk of open-heart surgery.

More than 400,000 people worldwide have received Edwards SAPIEN TAVR.

Patient Impact: TAVR Today

96% of low-risk patients were discharged home from the hospital with TAVR compared to 7.3% with surgery.

The survival rate at 1 year for patients at low-risk of open-heart surgery who received the SAPIEN 3 valve.

Edwards SAPIEN valves are the most widely used transcatheter heart valves in the world.

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2. www.newheartvalve.com/what-is-aortic-stenosis
5. Lester J et al. CHEST 1998;113(4):1109-1114.
7. The PARTNER 3 Trial unadjusted clinical event rates for TAVR with the SAPIEN 3 valve, AT population (n=1,000)
8. 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.
9. Indication: 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.
10. The major risks of TAVR are similar to open-heart surgery and include death, stroke, bleeding and vascular complications.

For consumer information, please visit NewHeartValve.com.

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