

# Edwards SAPIEN Transcatheter Heart Valve

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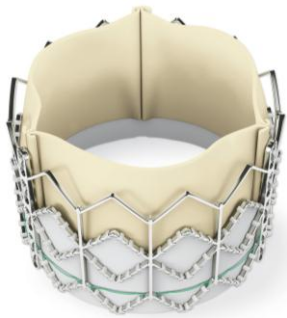
The Edwards SAPIEN Transcatheter Heart Valve is approved by the U.S. Food and Drug Administration (FDA) as a therapy for patients with severe symptomatic calcified native aortic valve stenosis who have been determined by a heart team that includes an experienced cardiac surgeon and cardiologist to be **inoperable** or **high risk** for open-chest surgery to replace their diseased aortic heart valve. Patients who are candidates for this procedure must not have other conditions that would make them too sick to experience the expected benefit from fixing their aortic stenosis (AS).

This procedure enables the placement of a balloon-expandable heart valve into the body with a tube-based delivery system (catheter). The valve is designed to replace a patient's diseased native aortic valve without traditional open-chest surgery and while the heart continues to beat – avoiding the need to stop the patient's heart and connect them to a heart-lung machine which temporarily takes over the function of the heart and the patient's breathing during surgery (cardiopulmonary bypass).

For both **inoperable and high-risk** patients, the valve is approved to be delivered with the RetroFlex 3 Delivery System through an artery accessed through an incision in the leg (transfemoral procedure). For **high-risk** patients who do not have appropriate access through their leg artery, the valve is approved to be delivered with the Ascendra Delivery System via an incision between the ribs and then through the bottom end of the heart called the apex (transapical procedure).

The Edwards SAPIEN valve is the only approved transcatheter aortic valve replacement (TAVR) therapy in the U.S., and select hospitals are now performing the procedure on qualified inoperable and high-risk patients.

## Features of the Edwards SAPIEN Transcatheter Heart Valve



- The flaps of tissue (valve leaflets) that open and close to regulate the flow of blood in one direction are sewn onto a balloon-expandable stainless steel frame.
- During the procedure, the valve is crimped down to the approximate diameter of a pencil and then delivered into the body via the RetroFlex 3 transfemoral or Ascendra transapical delivery system.
- The delivery system is designed to allow for controlled placement of the valve, to minimize impact to surrounding structures within the heart.
- Once in place, the Edwards SAPIEN Transcatheter Heart Valve is intended to function like a normal, healthy valve with proper blood flow.

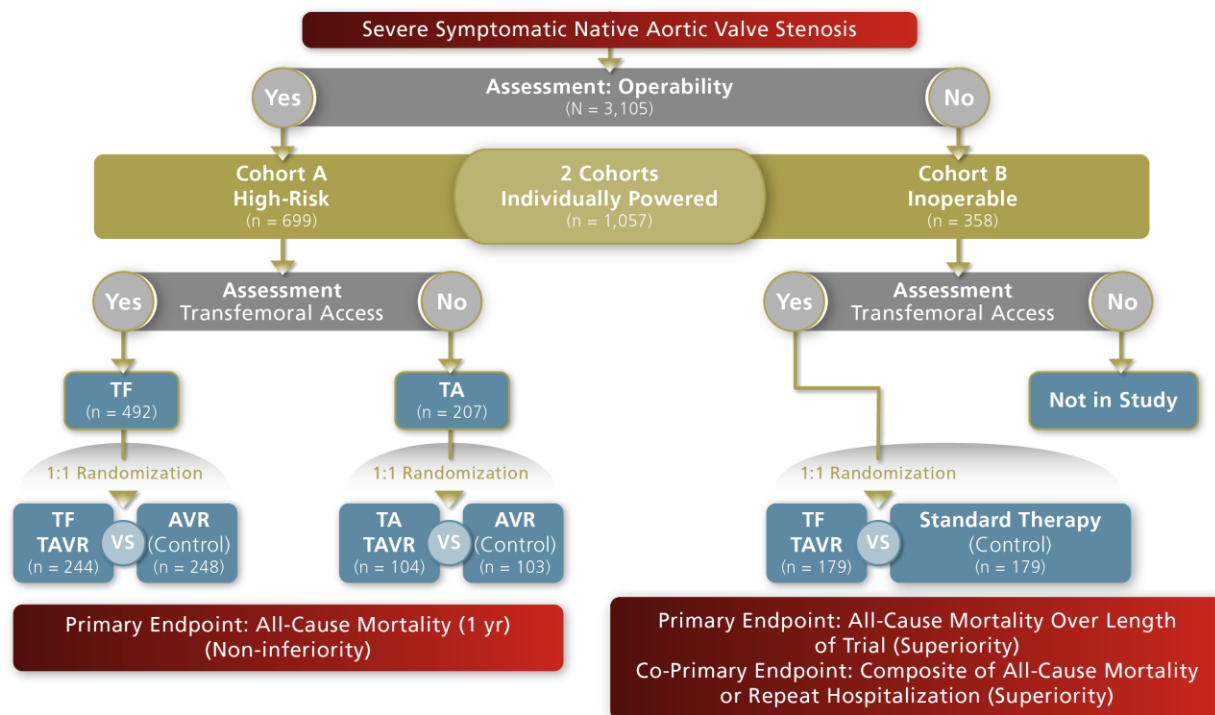
## Clinical Data

The safety and effectiveness of the Edwards SAPIEN valve were evaluated in a randomized, controlled pivotal trial called The PARTNER Trial. The name of the trial signifies the important partnership between cardiac surgeons and interventional cardiologists who were brought together to collaborate on the evaluation, procedure and follow-up treatment of patients using a multi-disciplinary, Heart Team approach.

A total of 1,057 patients were studied in The PARTNER Trial in two separate groups: **Cohort A** and **Cohort B**. Cohort A, or the “high risk” group, included 699 patients who were deemed high risk for surgery but still determined to be candidates for an open-chest procedure to replace their aortic heart valve. Cohort B, or the “inoperable” group, included 358 patients who were deemed not candidates for an open-chest procedure because of factors such as age, history of heart disease, frailty or other health issues.

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## TWO INDIVIDUALLY STRATIFIED AND POWERED COHORTS



AVR = aortic valve replacement

TF = transfemoral

TA = transapical

Data from both the high risk and inoperable study groups in The PARTNER Trial were published in four separate manuscripts in *The New England Journal of Medicine*, and analyses of this published data demonstrated that:

- Inoperable patients treated with the Edwards SAPIEN valve had a significantly higher survival rate than patients treated with standard medical therapy.
- Survival of high-risk patients treated with the Edwards SAPIEN valve was equivalent to those treated with open-chest surgery.
- Quality of life was improved in inoperable patients treated with the Edwards SAPIEN valve via the transfemoral route compared to patients treated with standard medical therapy.
- In comparing transfemoral TAVR with surgery in high-risk patients, TAVR patients felt better at one month, and had comparable results at one year to open-chest surgery. With the transapical approach, TAVR patients did not demonstrate a quality of life benefit at one month; the transapical and surgical groups showed comparable results at one year.
- In inoperable patients, the data demonstrated TAVR was very cost-effective given the life years added and the quality of life improvements. For high-risk patients, transfemoral access was shown to be more cost-effective than open-chest surgery.

The Edwards SAPIEN valve is approved for use in adult patients with severe, symptomatic native aortic valve stenosis who have been determined to be inoperable or high-risk for open-chest surgery and who meet other qualifications. TAVR is a significant procedure involving general anesthesia, and placement of the Edwards SAPIEN valve is associated with specific contraindications as well as serious adverse effects, including risks of death, stroke, damage to the artery used for insertion of the valve, major bleeding, and other life-threatening and serious events. In addition, the longevity of the valve's function is not yet known.

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Please refer to the Instructions for Use or Patient Brochure for complete information on warnings, contraindications and serious adverse events.

## More Information

More information about the TAVR procedure can be found at [www.edwards.com](http://www.edwards.com).

## References

1. Leon MB, Smith CR, Mack M, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med*. 2011;364(23):2187-98.
2. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med*. 2010;363(17):1597-1607.
3. Makkar RR, Fontana GP, Jilaihawi H, et al. Transcatheter aortic-valve replacement for inoperable severe aortic stenosis. *N Engl J Med*. 2012;366(18):1696-704.
4. Kodali SK, Williams MR, Smith CR, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. *N Engl J Med*. 2012;366(18):1686-95.

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