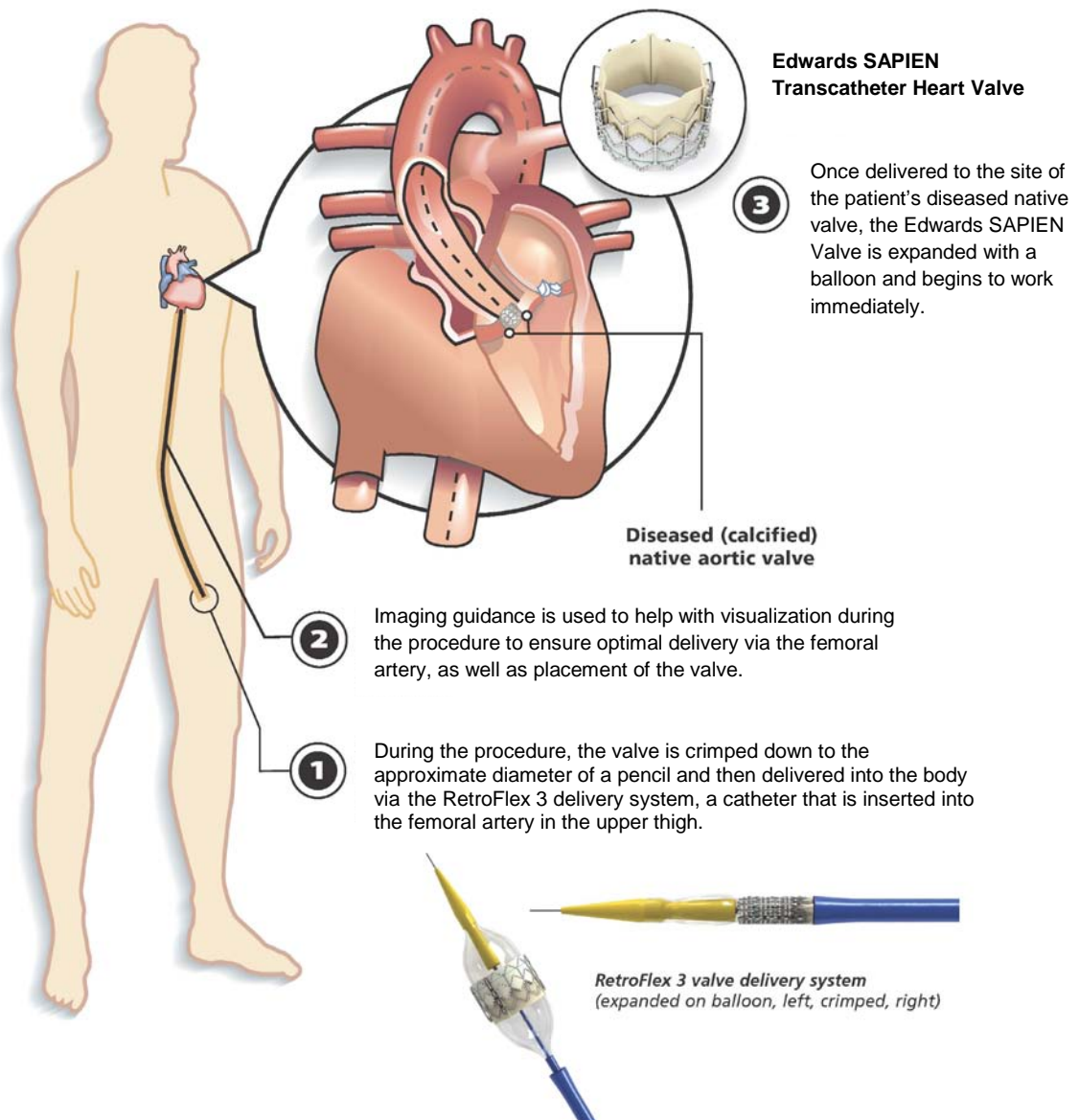


Fact Sheet: Edwards SAPIEN Transcatheter Aortic Heart Valve

In November of 2011, the U.S. Food and Drug Administration (FDA) approved the Edwards SAPIEN Transcatheter Heart Valve for the treatment of patients with severe symptomatic native aortic valve stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement, and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis. The Edwards SAPIEN Valve is the first transcatheter aortic valve replacement (TAVR) therapy approved for use in the U.S., and select hospitals are now performing the procedure on qualified patients.

This transcatheter procedure enables the placement of a collapsible aortic heart valve into the body via the catheter-based RetroFlex 3 transfemoral delivery system, which allows the Edwards SAPIEN valve to be inserted via the femoral artery in the thigh. The valve is designed to replace a patient's diseased native aortic valve without traditional open-heart surgery and while the heart continues to beat – obviating the need for cardiopulmonary bypass.

The Transcatheter Aortic Valve Replacement Transfemoral Approach



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Features of the Edwards SAPIEN 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 delivery system.
- The delivery system is designed to allow for controlled placement, 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 study 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 1,058 patients in The PARTNER Trial were studied in two separate groups. The “high risk” group included patients who were high risk for surgery but still determined to be candidates for an open-chest procedure to replace their aortic heart valve. The Edwards SAPIEN valve remains investigational for the treatment of these high-risk patients.

The “inoperable” group – the patient population for which the therapy is now approved – included patients who were not candidates for an open-chest procedure because of factors such as age, history of heart disease, frailty or other health issues.

In September of 2010, *The New England Journal of Medicine* published results from the “inoperable” study group (Cohort B), which showed that the Edwards SAPIEN Valve had a significantly lower mortality rate than standard medical therapy.¹ Specifically:

- Seven out of every 10 inoperable patients with severe aortic stenosis were alive one year after the procedure.
- In comparison, only five out of every 10 patients who did not receive a new valve (part of the control group) were alive at one year.
- Patients treated with the Edwards SAPIEN Valve had improved heart function and improved quality of life at one year, as compared to patients not treated with the valve.

The Edwards SAPIEN Transcatheter Heart Valve is approved for the treatment of adult patients with severe symptomatic native aortic valve stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement, and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis. Transcatheter aortic valve replacement 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.

More Information

More information about the TAVR procedure can be found at www.edwards.com.

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References

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2. Ye J, Cheung A, Lichtenstein SV, et al. Transapical transcatheter aortic valve implantation: follow-up to 3 years. *J Thorac Cardiovasc Surg* 2010; 139:1107-1113.
3. U.S. Food and Drug Administration (November 2, 2011). FDA approves first artificial aortic heart valve placed without open-heart surgery [press release]. Retrieved from <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm278348.htm>

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