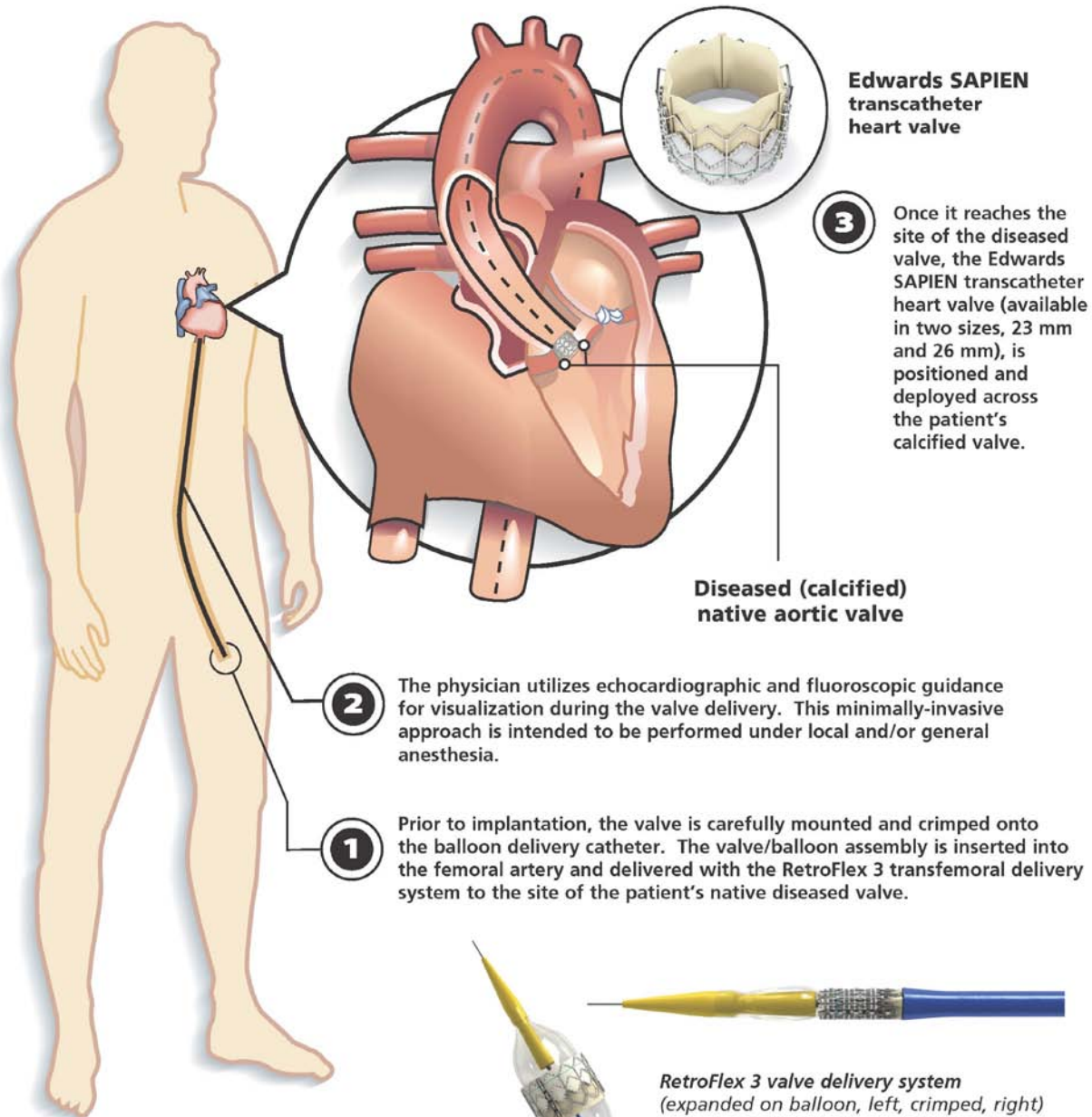


# Edwards SAPIEN Transcatheter Aortic Heart Valve

The Edwards SAPIEN valve is a collapsible aortic heart valve that can be introduced into the body via a catheter-based delivery system. 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. The valve can be implanted in patients using the transfemoral technique (delivered via the femoral artery) or transapical technique (delivered via a small incision between the ribs).

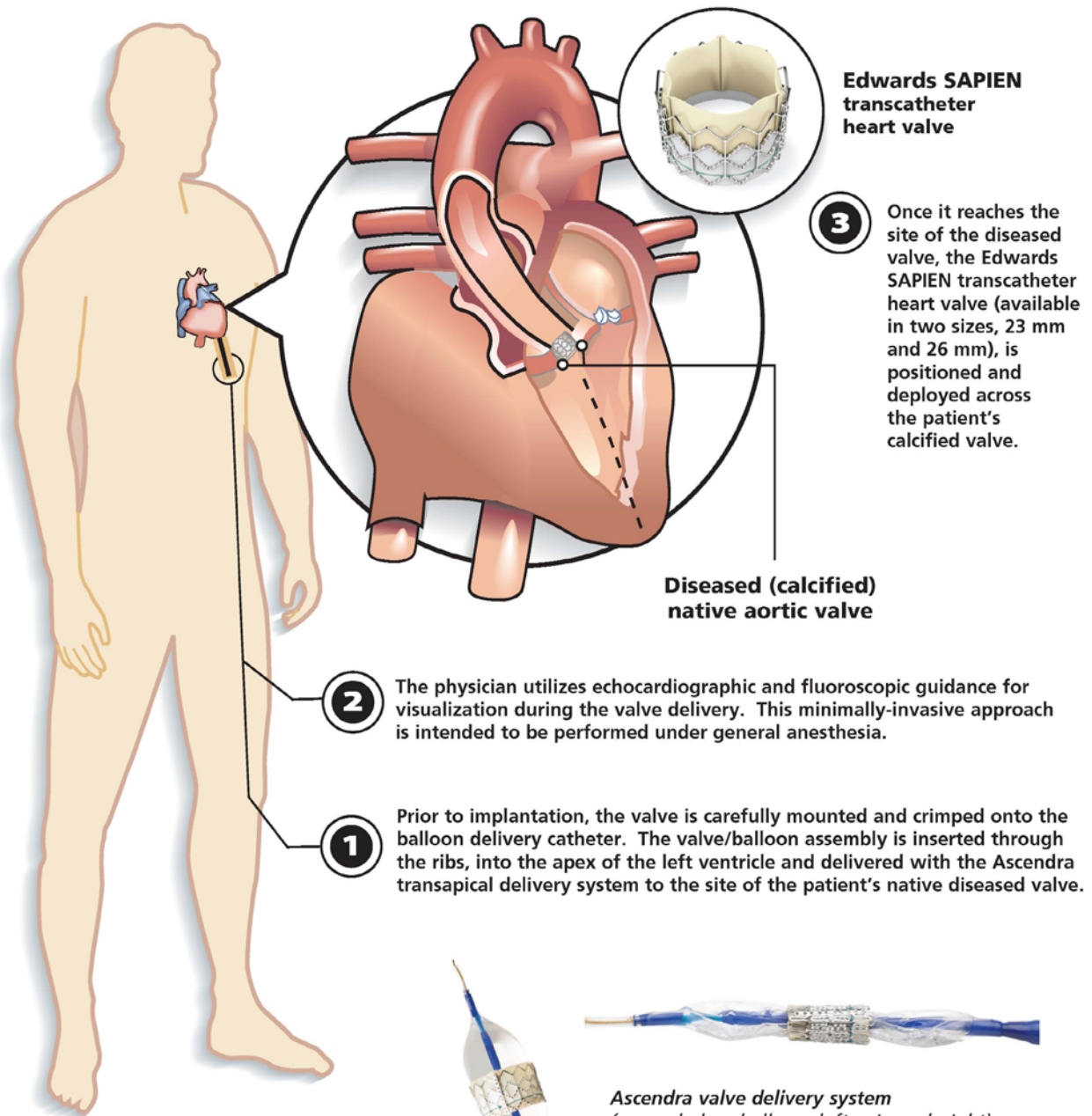
## Transfemoral Approach



**CAUTION:** Investigational device. Limited by Federal (USA) Law to investigational use. Investigational device to be used by qualified investigators only.

# Edwards SAPIEN Transcatheter Aortic Heart Valve

## Transapical Approach



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# Edwards SAPIEN Transcatheter Aortic Heart Valve

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## Valve Features:

- The valve leaflets are sewn onto a balloon-expandable stainless steel frame.
- The valve is crimped down to the approximate diameter of a pencil before being introduced into the body via a catheter-based delivery system.
- The delivery system design allows for controlled placement, minimizing impact to surrounding structures.
- The leaflets function like a normal, healthy valve to ensure proper blood flow (hemodynamics).

The Edwards SAPIEN valve is a less-invasive alternative for patients with severe aortic stenosis to address their life-threatening disease progression. It is an investigational device being evaluated for patients considered high-risk or not candidates for traditional open-heart surgery as part of The PARTNER Trial, the world's first randomized, controlled pivotal trial of transcatheter aortic valve replacement (TAVR).

## Edwards' Heart Valve History

The Edwards SAPIEN transcatheter valve builds upon Edwards Lifesciences' more than 50 years of continuous refinement in surgical heart valve technology, and successful collaboration in device development with clinicians. This foundational experience in heart valve technology has translated into demonstrated durability of the company's surgical heart valves and positive patient outcomes – establishing Edwards as a leader in the science of heart valves.

## Tissue and Mechanical Valves

There are two general types of valves used for aortic valve replacement: mechanical valves and tissue valves. Mechanical valves have proven durability, but patients must take blood thinning medication (anticoagulation therapy) to prevent the formation of blood clots, which requires regular monitoring (usually every three to four weeks). As severe bleeding is a risk while taking blood thinners, patients must exercise caution when participating in certain activities and avoid situations that increase the risk of injury. Tissue valves do not require lifetime anticoagulation therapy after implantation. The most commonly used aortic heart valves in the U.S. today are tissue valves, which have proven durability of up to 20 years.

## More than 50 Years of Experience in Surgical Valves

Edwards Lifesciences established its leadership in heart valve therapy first with the development of the Starr-Edwards Mechanical Valve and later with the world's most widely implanted tissue valves, the PERIMOUNT family of valves. Decades of refinement through experience, scientifically rigorous studies and further collaboration with clinicians – including with those who performed the first successful TAVR on a human patient in April 2002 – led to the innovation of the Edwards SAPIEN transcatheter valve in 2006. The manufacturing processes used for the Edwards SAPIEN valve are based on the company's foundational surgical tissue valves, which were developed from Edwards' rich experience in heart valve therapy.

## **Edwards SAPIEN Transcatheter Aortic Heart Valve**

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### **Edwards' Next-Generation Transcatheter Valve**

In 2009, Edwards' second commercially available transcatheter valve, the Edwards SAPIEN XT valve, was introduced into clinical use in Europe. The valve features a lower profile delivery system, designed to treat a broader population of patients and to reduce vascular complications. In 2010, the valve received CE Mark and was also approved to be studied in Japan's first clinical trial of a transcatheter heart valve – adding another first to Edwards' series of landmark transcatheter heart valve trials and further extending the company's global leadership in transcatheter valve technology. Edwards received conditional FDA approval to initiate a randomized, controlled U.S. clinical trial to evaluate the safety and effectiveness of the Edwards SAPIEN XT valve in patients with severe aortic stenosis.

To date, more than 12,000 patients have been implanted with the Edwards SAPIEN valves by multi-disciplinary heart teams worldwide.

### **Trademarks**

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