



**PRODUCT: Edwards SAPIEN 3 Ultra™  
Transcatheter Heart Valve System**

**COMPANY:** Edwards Lifesciences

**THERAPEUTIC AREA & INDICATION:**  
Aortic stenosis

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#### ABOUT THE PRODUCT

The Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System was approved in 2019 for the relief of aortic stenosis in low-risk patients with symptomatic heart disease due to severe native calcific aortic stenosis. Aortic stenosis is a severe heart condition in which the opening of the aortic valve narrows, blocking blood flow from the heart to the rest of the body. The SAPIEN 3 Ultra valve is a less invasive catheter-based therapy, performed on a beating heart. The SAPIEN platform of valves is the most clinically studied transcatheter valve in history. More than 650,000 patients globally have benefited from TAVR.