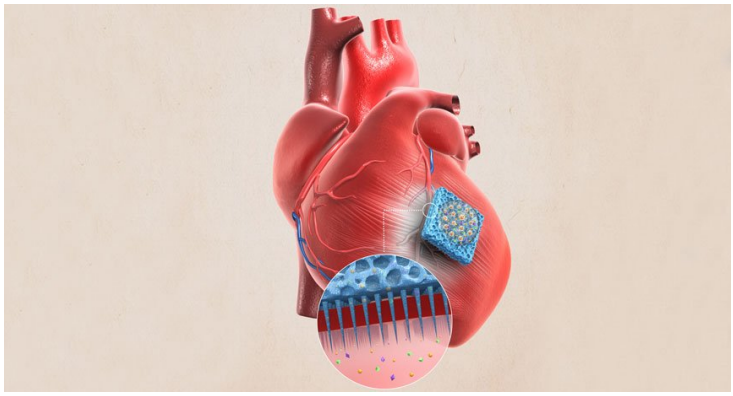
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Edwards' SAPIEN 3 Ultra Transcatheter Heart Valve gets FDA nod

28 December 2018 | News

The SAPIEN 3 Ultra system builds on Edwards' decades of engineering and experience in the development of tissue heart valves, and the proven benefits of the Edwards SAPIEN valves



Edwards Lifesciences Corporation, the global leader in patient-focused innovations for structural heart disease and critical care monitoring, today announced that the SAPIEN 3 Ultra system has received U.S. Food and Drug Administration (FDA) approval for transcatheter aortic valve replacement in severe, symptomatic aortic stenosis patients who are determined to be at intermediate or greater risk of open-heart surgery.

"The advanced SAPIEN 3 Ultra system features enhancements on the valve and a new delivery system to address the needs of both patients and clinicians, building on our best-in-class performance of SAPIEN 3 to further advance and improve patient care," said Larry L. Wood, Edwards' corporate vice president, transcatheter heart valves. "We look forward to introducing the SAPIEN 3 Ultra system to U.S. patients."

The SAPIEN 3 Ultra system builds on Edwards' decades of engineering and experience in the development of tissue heart valves, and the proven benefits of the Edwards SAPIEN valves.