

**Company**

Edwards Lifesciences

**Drug or Device Name**

Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestant

**Category**

Medical Technology

**Compound/Technical Name**

Transcatheter Heart Valve with Pulmonic Adaptive Prestant

**Trade Name**

Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestant

**Date of Approval**

12/16/2021

**Therapeutic Categories**

Medical device, implant, cardiovascular therapy

**Indications**

The Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestant is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation as measured by echocardiography, who have a native or surgically repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement.

**Background**

Congenital Heart Disease (CHD) is one of the most common birth defects in the United States, reported in approximately eight of every 1000 newborns. Right ventricular outflow tract (RVOT) defects such as pulmonary valve stenosis, Tetralogy of Fallot, and double outlet right ventricle are common in this population and may represent as many as 20% of those with CHD. People with congenital heart defects typically face the burden of multiple open-heart surgeries over the course of their lives, often beginning at birth and continuing roughly every 10 to 20 years. At some point, some CHD patients may need their RVOT replaced with a bioprosthetic valve conduit, or have their pulmonary valve replaced with a surgical bioprosthetic valve. Over time, a patient's conduit or surgical valve may become narrowed or may begin to leak blood (pulmonary regurgitation). When this happens, it usually means it is time for a new pulmonary valve, which must then be again replaced at the end of its lifespan. Transcatheter pulmonic valve (TPV) therapy is a less invasive procedure for replacing the pulmonary valve in either a dysfunctional conduit or failing surgical tissue valve. As surgical risk increases with each open-heart surgery, minimally invasive options may reduce the overall number of open-heart surgeries a congenital patient undergoes and enable them to live a more normal life. The Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestant received FDA approval

in December of 2021. The innovative Alterra Adaptive Prestent provides a docking mechanism for the deployment of the industry leading SAPIEN 3 Transcatheter Heart Valve in the pulmonic position, providing a much-needed less invasive therapy option for a vulnerable patient population that would otherwise face repeated open-heart surgeries.

## Development

Edwards Lifesciences is committed to partnering with clinicians, colleagues, and patients to develop innovative therapies for those suffering from structural heart disease and the critically ill. Following the FDA approval in 2011 of the SAPIEN transcatheter heart valve and its demonstrated real-world success in providing a less invasive option for aortic valve replacement, Edwards began working to adapt this breakthrough technology to address the needs of congenital heart disease patients. Edwards believed the right approach was to leverage the proven SAPIEN platform – which at this point was supported by clinical data from trials involving thousands of aortic patients – with an adaptive device that compensated for the unique anatomy of the pulmonary valve in the CHD population. The primary benefit of using the SAPIEN platform with a first of its kind developed adaptive prestent was that pulmonic patients would benefit from the SAPIEN platform's track record as the most clinically studied THV in history, and the continual improvements made to the SAPIEN valve. The ALTERRA clinical trial was initiated in August of 2017, enrolling 85 participants in a single arm, prospective, multi-center study. The trial yielded impressive results with a 96% implant success rate and 0% cardiovascular death or endocarditis at 1 year. The subsequent FDA approval of the Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent was highly anticipated by congenital cardiologists as it expanded the range of congenital patients who could now be treated with the SAPIEN platform. In the handful of months since approval, more than 68 patients have undergone implantation worldwide. For many patients, this new therapy option could mean avoiding open heart surgery in their late teens or early 20s, preventing disruption and improving quality of life during critical years of school, early career and family development.

## Innovation

Transcatheter pulmonic valve (TPV) therapy utilizing the Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent leverages a proven breakthrough technology to serve an expanded patient population with heretofore limited treatment options, that typically faces the burden of multiple open-heart surgeries, oftentimes beginning at birth. The Alterra prestent is designed to accommodate the wide variety of very unique anatomies encountered in RVOT patients and provide a circular, semi-rigid landing zone to place a SAPIEN 3. This approach of adapting a proven technology to a new patient population presents manifest advantages. The SAPIEN platform of valves is the most clinically studied THV in history, with more than 30,000 patients treated in clinical trials and registries in over 65 countries around the world, 10,000 patients studied, and six separate manuscripts published in The New England Journal of Medicine. To date, SAPIEN TAVR has touched more than 750,000 lives around the world. Additionally, creating the Alterra prestent to leverage the clinically proven SAPIEN 3 valve includes this small but important patient population within the scope of future improvements and innovations to the SAPIEN platform. Edwards invests approximately 17% of revenues in research and development to continually innovate and improve its products. The system's innovative design ensures future CHD patients will benefit from these advances and opens expanded treatment options for lifetime management of congenital heart disease. This patient population has historically been the subject of very little medical device innovation. For any parent that is faced with this disease in their child, the impact that the Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent can have on the life of their child by providing a much-needed

less invasive therapy alternative to open-heart surgeries is incredible.

### Pubmed

Suntharos P, Prieto LR. Percutaneous Pulmonary Valve Implantation in the Native Right Ventricular Outflow Tract Using a 29-mm Edwards SAPIEN 3 Valve. *World journal for pediatric & congenital heart surgery*. 2017;8(5):639- 642. DOI: 10.1177/2150135116655125. Epub Nov 2016. Faccini A, Chessa M, Aljoufan M. Management of balloon rupture during a percutaneous pulmonary valve implantation procedure. *Cardiology in the young*. 2018;1-3. DOI: 10.1017/S1047951118001051. Epub Jul 2018. Guzeltas A, Tanidir IC, Gokalp S, Haydin S. Hybrid transcatheter pulmonary valve implantation: The first case series from Turkey. *Anatolian journal of cardiology*. 2018;20(3):190-191. DOI: 10.14744/AnatolJCardiol.2018.06981. No Epub. Auzina L, Lubaua I, Ligere E, et al. Initial experience with Edwards SAPIEN valve transcatheter implantation in native RVOT in Latvia. *Acta Med Litu*. 2020;27(1):10-16. doi: 10.6001/actamedica.v27i1.4261.

### Attachments

- 1656613193Alterra\_FDA\_approval.pdf
- 1656615252JACC\_Alterra\_Feasibility\_Study.pdf