

Category

Best Medical Technology

Drug / Device Name

Edwards SAPIEN 3 Ultra RESILIA Transcatheter Aortic Heart Valve

Compound/ Tech Name

Transcatheter Heart Valve

Trade Name

Edwards SAPIEN 3 Ultra RESILIA Transcatheter Aortic Heart Valve

Date of Approval

2022-07-28

Indications

The Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team to be appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for patients with symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic valve, a surgical bioprosthetic mitral valve, or a native mitral valve with an annuloplasty ring who are judged by a Heart Team to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality $\geq 8\%$ at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).

Therapeutic Categories

Medical device, implant, cardiovascular therapy

Attached Files:

- P140031S141 US FDA Approval Letter SAPIEN 3 Ultra RESILIA 2.pdf

Background information and need for drug/device

Edwards Lifesciences has more than 60 years of expertise in the treatment of heart valve disease and is uniquely focused on developing innovative solutions to improve the lives of patients suffering from this condition. When the Carpentier-Edwards bioprosthetic heart valve was introduced in 1981, its use of bovine pericardium leaflets represented an advancement over the Starr-Edwards mechanical valve by eliminating the need for life-long use of blood thinners, but introduced the complication of shorter durability of the bioprosthetic valve. Since then, Edwards has tirelessly innovated to continually improve the durability of its valves, which is a vital concern of patients and increasingly important as patients live longer with their replacement valve.

Decades of research have been dedicated to determining the primary causes of structural valve deterioration in both surgical and transcatheter heart valves that lead to a reintervention. Successive generations of valves have been developed to address these causes. One of the drivers of structural valve deterioration today is the same that causes failure of the native valve: calcification. The one of kind RESILIA tissue was developed through 20 years of research and development to address this issue.

RESILIA tissue features advanced anti-calcification technology that in recent studies has demonstrated freedom from structural valve deterioration at 7 years. First introduced in 2017 on Edwards' INSPIRIS RESILIA surgical aortic valve, RESILIA tissue has been incorporated into additional Edwards platforms and, in 2022, was approved for use with the industry leading transcatheter heart valve to produce the next generation SAPIEN 3 Ultra RESILIA.

In addition to the calcium blocking properties that provide the potential to extend the durability of the SAPIEN 3 Ultra RESILIA valve, RESILIA allows dry tissue packaging conditions that simplify procedures during implantation. Dry storage of bioprosthetic tissue valves is only available with RESILIA tissue valves due to its proprietary technology.

The SAPIEN 3 Ultra RESILIA valve is a prime example of Edwards' continued focus on innovating to meet the current and future needs of patients to help them live longer, healthier and more productive lives.

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History of the development of the drug/device

Since the introduction of the Carpentier-Edwards bioprosthetic heart valve in 1981, Edwards has tirelessly innovated to continually improve the durability of its valves. The first-generation valve featured neutralogic fixation intended primarily for tissue preservation. This was followed by XenoLogiX treatment in 1985 that added phospholipid extraction and terminal liquid sterilization to the previous tissue preservation treatment. The first attempt to address calcification of the valve tissue came in the form of the ThermaFix Process in 2004 that added glutaraldehyde stabilization to the XenoLogiX treatment.

It was shortly after the ThermaFix introduction that Edwards began work on RESILIA to further improve anti-calcification technology. Research and development culminated in the COMMENCE trial – a prospective, non-randomized multicenter, single-arm trial conducted at 27 sites across the United States and Europe with 689 patients – and the FDA approval of the INSPIRIS RESILIA surgical aortic valve in 2017. Seven-year follow up on COMMENCE trial patients showed 99.3% freedom from structural valve deterioration.

On a parallel track to the development of RESILIA tissue, Edwards was developing the breakthrough SAPIEN transcatheter heart valve. In November 2011, following results of the groundbreaking PARTNER Trial published in The New England Journal of Medicine, Edwards introduced the SAPIEN valve, the first FDA-approved transcatheter aortic heart valve for the treatment of inoperable patients suffering from AS. Following its successful adoption, the FDA approved two next generation transcatheter heart

valves, SAPIEN XT and SAPIEN 3, which were also approved for pulmonic and intermediate risk patients. In 2019, the FDA approved SAPIEN 3 Ultra for in the treatment of low-risk patients, based on the superior outcomes to surgery as shown in the PARTNER 3 Trial published in The New England Journal of Medicine.

The creation of the SAPIEN 3 Ultra RESILIA combines Edwards' 40 years of tissue expertise with the market-leading SAPIEN 3 Ultra transcatheter valve and delivers patients with severe AS crucial improvements: a less invasive alternative to surgery with the potential for a longer lasting valve.

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- 1593383067IR_HR_nejmoa1008232.pdf
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Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition

When Edwards introduced the SAPIEN transcatheter heart valve, the ability to replace the aortic valve without surgery was a breakthrough in the treatment of aortic stenosis that saved the lives of thousands of patients with no other alternative. In the decade since the SAPIEN valve was approved by the FDA in 2011, the Edwards SAPIEN transcatheter heart valve has received expanded indications to now treat severe symptomatic aortic stenosis (ssAS) patients at all risk levels. Edwards has also continued to innovate and has improved SAPIEN through successive generations of valves that now provide outcomes that surpass surgical valve replacement.

However, the durability of transcatheter valves has remained a lingering question and may be the last hurdle to TAVR becoming the standard of care for severe aortic stenosis. As one of the leading causes of SVD, addressing calcification is key to overcoming the durability hurdle and providing thousands of patients with the confidence to choose the therapy that fits their needs. RESILIA tissue builds on Edwards' 40 years of tissue expertise to deliver the potential for a longer lasting transcatheter valve. RESILIA tissue builds on the previous best in class ThermaFix process, adding an advanced calcium-blocking technology that targets calcium-attracting free aldehydes with a stable capping process. Recent data from the COMMENCE trial examining the performance of RESILIA tissue revealed this technology demonstrated 99.3% freedom from SVD at 7 years.

The Edwards SAPIEN 3 Ultra RESILIA combines these two powerful technologies to offer patients the potential for a longer lasting valve with superior outcomes. As TAVR patients have longer life expectancies with expanded indications and awareness, lifetime management of these patients becomes more essential. With the promise of RESILIA tissue to address one of the leading causes of SVD, SAPIEN 3 Ultra RESILIA provides outcomes superior to surgery, enables future coronary access and potentially extends durability to extend the life of the first bioprosthetic valve before a second intervention may be required. The SAPIEN 3 Ultra RESILIA's proven advantages empowers clinicians and patients to select a valve that addresses key issues on the lifetime management of aortic stenosis and allows for shared decision making between physician and patient with these critical advancements in TAVR technology.

Attached Files:

- 1593393984PARTNER_3.pdf
- 7yr outcomes following AVR with a novel tissue bioprosthesis Beaver et al. AATS 2023 PPUS8220
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Please provide appropriate references (ie Pubmed links)

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