

Edwards EVOQUE Transcatheter Tricuspid Valve Replacement System

Category:

Best Medical Technology

Company Name:

Edwards Lifesciences

Product/Solution Name:

Edwards EVOQUE Transcatheter Tricuspid Valve Replacement System

Compound/Tech Name:

Transcatheter Tricuspid Heart Valve

Trade Name:

Edwards EVOQUE Transcatheter Tricuspid Valve Replacement System

Corporate Name:

Edwards EVOQUE Transcatheter Tricuspid Valve Replacement System

Date of Approval:

2024-02-01

Indications:

The Edwards EVOQUE Transcatheter Tricuspid Valve Replacement System is indicated for the improvement of health status in patients with symptomatic severe TR despite optimal medical therapy (OMT), for whom tricuspid valve replacement is deemed appropriate by a heart team.

Therapeutic Areas:

Medical device, implant, cardiovascular therapy

General Information File Document upload:

EVOQUE IFU DOC0211944A USA Commercial.pdf

Background information and need for drug / device:

Edwards Lifesciences has more than 65 years of expertise and is the global leader in patient-focused medical innovations for the treatment of structural heart disease. There are four valves that pump blood through the chambers of the heart, with the tricuspid valve being on the right side of the heart. Tricuspid Regurgitation (TR) happens when the leaflets of the tricuspid valve do not close properly, causing blood to flow backward from the lower chamber (ventricle) into the upper chamber (atrium). This makes the heart work harder to move blood through the valve.

An estimated 1.5 million patients in the US suffer with moderate or worse TR, yet these patients are often undertreated (>90%). TR exacts a heavy toll on patients' lives, often resulting in debilitating symptoms such as swollen lower extremities, limited mobility, difficulty breathing, fatigue, and poor sleep. Patients suffering with symptomatic TR can experience a significant reduction in their quality of life.

Long considered the \"forgotten valve,\" few treatment options have been available to patients suffering with TR, including medications that address some symptoms (but don't cure or fix the valve), and open-heart surgery to repair or replace the damaged valve. An estimated 20% of patients with severe TR die within one year of diagnosis.

With a mission to develop novel therapies that transform treatment for underserved patients in the structural heart space, Edwards developed and introduced the world's first Transcatheter Tricuspid Valve Replacement Therapy in October 2023 when it received CE Mark for its EVOQUE Transcatheter Tricuspid Valve Replacement System, earning FDA approval in February 2024 to make the EVOQUE system the first Transcatheter Tricuspid Valve Therapy available in the United States.

The TRISCEND II pivotal trial demonstrated superior clinical and quality-of-life benefits with the EVOQUE system for severe tricuspid regurgitation in one-year primary endpoint outcomes, as compared to patients treated with optimal medical therapy alone. The EVOQUE system is currently approved for use in 14 countries with thousands of patients treated to date.

Background File Document upload:

EVOQUE Patient Brochure_2025.pdf
EVOQUE HCP Brochure with 56.pdf

History of the development of the solution/product:

Already the market leader in transcatheter therapy solutions for the Aortic and Pulmonary valves, Edwards increased its commitment to and investment in the development of a portfolio of repair and replacement therapy options to treat a broad and underserved patient population suffering with Mitral and Tricuspid valve disorders. With progress being made on a transcatheter Mitral valve replacement system, the company began to investigate if the technology could be adapted and applied to the Tricuspid valve. A team redesigned and reconfigured the existing delivery system, established new valve testing systems, and engaged with leading clinicians to develop the procedure and establish patient screening and imaging protocols. Early bench and animal testing indicated the system's potential.

The Edwards EVOQUE system received FDA Breakthrough Designation in December 2019 and the TRISCEND Early Feasibility Study was initiated in May 2020 to evaluate the system's safety and performance in patients with symptomatic, moderate or greater TR. Two-year TRISCEND outcomes confirm the system's safety and performance, along with meaningful and sustained improvement in clinical, functional, and quality-of-life outcomes.

The TRISCEND II pivotal trial was initiated in April 2021 to evaluate the safety and effectiveness of the EVOQUE system with optimal medical therapy (OMT) compared with OMT alone in patients with severe TR. One-year primary endpoint outcomes from the TRISCEND II pivotal trial were presented as a late-breaker at the Transcatheter Cardiovascular Therapeutics (TCT) meeting in Oct. 2024 (and simultaneously published in The New England Journal of Medicine) and included the full cohort of 400 patients. The EVOQUE valve was successfully implanted in 95.4 percent of patients, and of those who received the valve, nearly all (95.3 percent) achieved almost complete TR elimination with \leq mild TR at one year, compared to 2.3 percent of patients receiving OMT alone. These TR reductions were associated with significant improvements in symptoms, function and Quality-of-Life (QoL) at one year, with favorable numerical outcomes in mortality and heart failure hospitalization. TRISCEND II trial one-year QoL outcomes also were presented as a late-breaker at TCT in Oct. 2024 and simultaneously published in the Journal of the American College of Cardiology.

Thousands of patients have been treated with the EVOQUE system to date. The EVOQUE system received CE Mark in October 2024 and FDA approval on February 1, 2024 and is currently approved for use in 14 countries.

Development File Document upload:

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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:

The Tricuspid valve has long been undertreated. Historically, no transcatheter treatment option was available for the Tricuspid valve, and the surgical community shied away from tricuspid valve replacement due to poor outcomes. This left few treatment options for the estimated 1.5 million US patients suffering with often debilitating symptoms of Tricuspid Regurgitation (TR). With the development and FDA approval of Edwards' EVOQUE Transcatheter Tricuspid Valve Replacement System, TR patients now have a treatment option with the potential to eliminate TR and improve their quality of life.

The EVOQUE valve has several key design features. The nitinol self-expanding frame comprises an inner structural frame, to which the leaflets and anchors are attached, and an outer frame, which is softer and designed to conform to the native valve anatomy. The inner frame diameter is fixed with a 28mm valve design, whereas the outer frame varies to produce four different valve sizes (44, 48, 52, and 56 mm), enabling treatment of a wide range of Tricuspid anatomies. There are nine ventricular anchors that engage the native leaflets, annulus, and subvalvular anatomy. The leaflets of the EVOQUE valve are made from Edwards' proven bovine pericardial tissue.

All four valve sizes utilize the same 28F (outer diameter) catheter-based delivery system. The procedure is conducted under general anesthesia, guided by Fluoroscopy imaging, and utilizes femoral transvenous access.

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Please provide appropriate references (PubMed, Abstract, Website):

<https://www.edwards.com/healthcare-professionals/products-services/transcatheter-mitral-tricuspid-technologies/evoque-tricuspid-valve-replacement-system>

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