Transcatheter Tricuspid Valve Replacement

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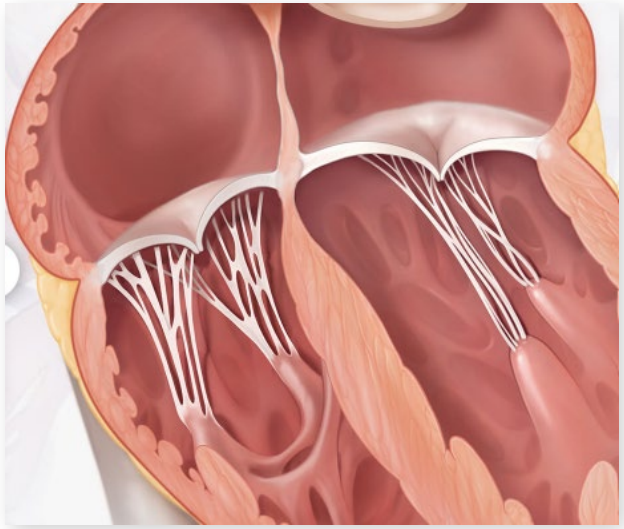
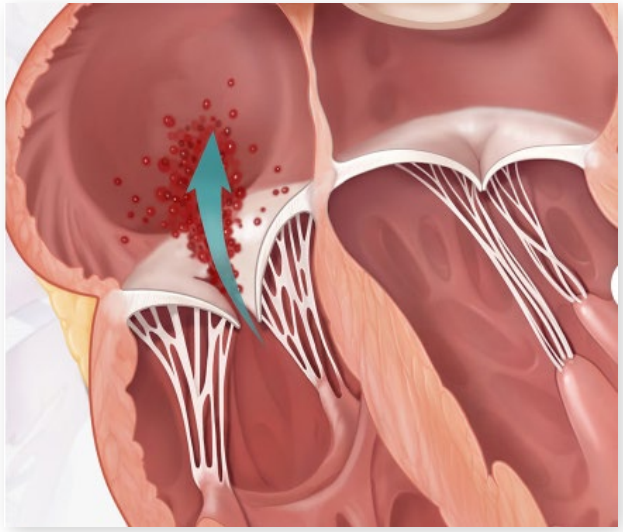
Background

Healthy Tricuspid Valve



Heart with Tricuspid Regurgitation



- Tricuspid regurgitation (TR) is a **heart valve disorder** caused by leaflets of the tricuspid valve not closing properly, allowing blood to flow back into the right atrium
- Several factors can **increase the risk of TR**, including infections, heart attack or failure, atrial fibrillation, pulmonary hypertension, heart disease including congenital heart disease, use of certain medications, or radiation

Treatment options & medical management

Patients with TR may experience multiple debilitating symptoms, including:

- Shortness of breath
- Significant abdominal and ankle swelling
- Fluid retention
- Chest pain

Although most patients with symptomatic TR are treated with diuretics to manage their condition,[1] there are several important limitations associated with the use of this treatment:

- May only temporarily treat symptoms[1]
- Not effective for all types of TR[1,2]
- Contribute to polypharmacy (multiple medication use) and pill burden[3]

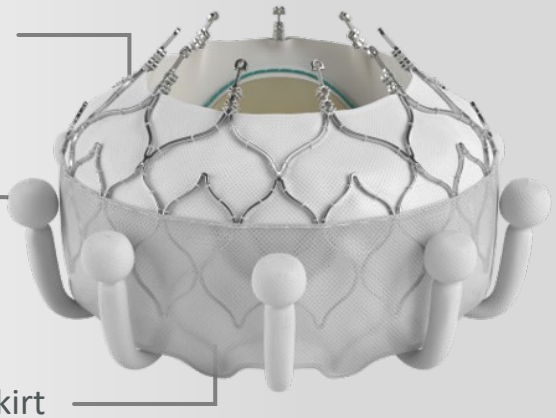
Sources: 1. Fender et al., 2018; 2. Otto et al., 2021; 3. Mastromarino et al., 2014.

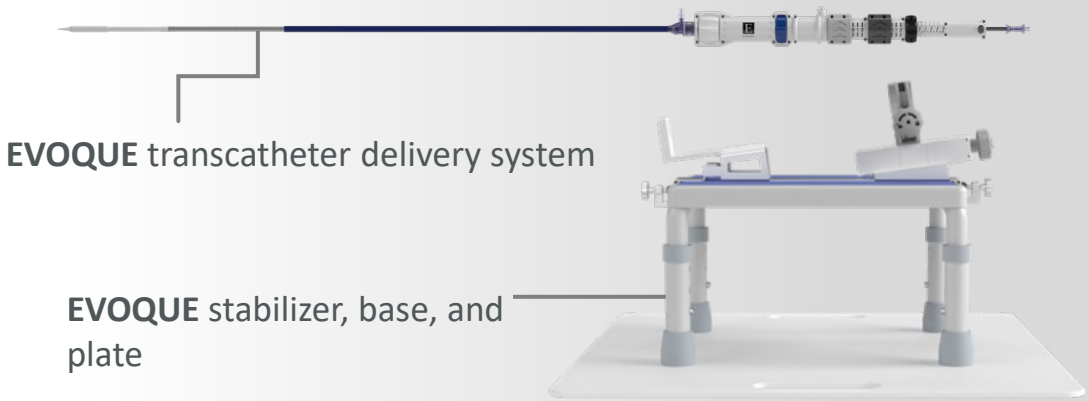
The Edwards EVOQUE tricuspid valve replacement system

The Edwards EVOQUE tricuspid valve replacement system is an innovative solution for patients with tricuspid regurgitation

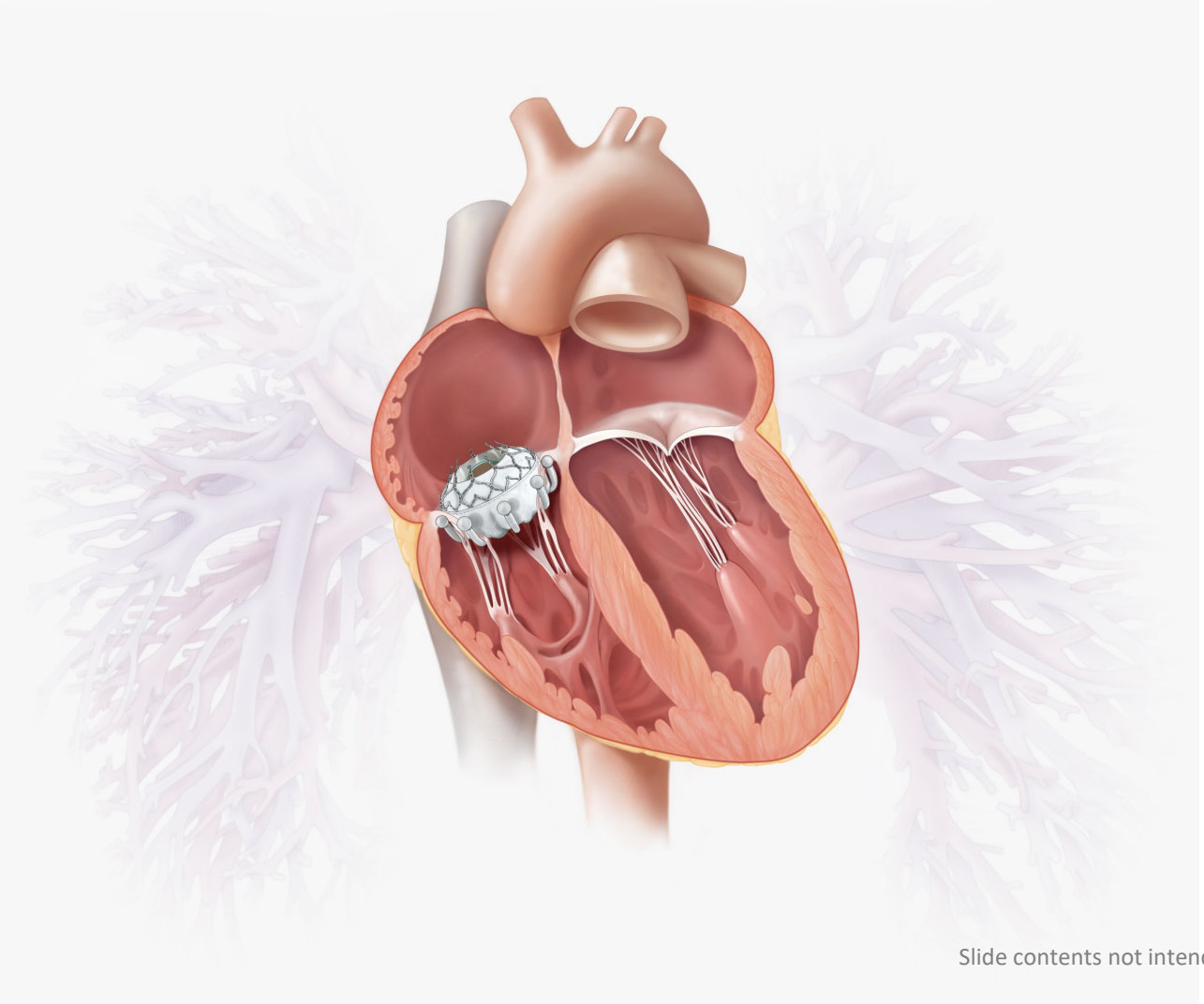
Key features of the bioprosthetic valve and delivery system:

- Atraumatic anchors are compatible with pre-existing pacing leads and respect the native anatomy
- Conforming nitinol frame contribute to retention force
- Multiple sizes offer treatment for a broad range of tricuspid pathologies and anatomies
- 28F transfemoral delivery system compatible with all valve sizes





Anatomical positioning of the implanted Edwards EVOQUE valve



The Edwards EVOQUE valve fully replaces the native tricuspid valve via a transcatheter approach

The 9 atraumatic anchors are used to capture the native leaflets and prevent paravalvular leakage

Transcatheter tricuspid valve replacement (TTVR) procedural steps (slide 1 of 2)

Procedure Step	Description
1	After general anesthesia is induced, the patient is intubated. A transesophageal echocardiography (TEE) probe is inserted and positioned to obtain appropriate views of the tricuspid valve.
2	Femoral vein access is obtained, after which, under fluoroscopic guidance, a guidewire is inserted and advanced across the tricuspid valve.
3	After the access site is dilated to accommodate the 28 French delivery system, the transcatheter delivery system (with bioprosthetic valve) is advanced over the guidewire into the right atrium of the heart. A combination of fluoroscopic and echocardiographic guidance is used to advance the valve delivery catheter via the vena cava to the native tricuspid valve.
4	The system is advanced across the tricuspid annulus and into the right ventricle (RV), and the position is confirmed for deployment of the valve within the tricuspid plane as determined by fluoroscopy and TEE.

Transcatheter tricuspid valve replacement (TTVR) procedural steps (slide 2 of 2)

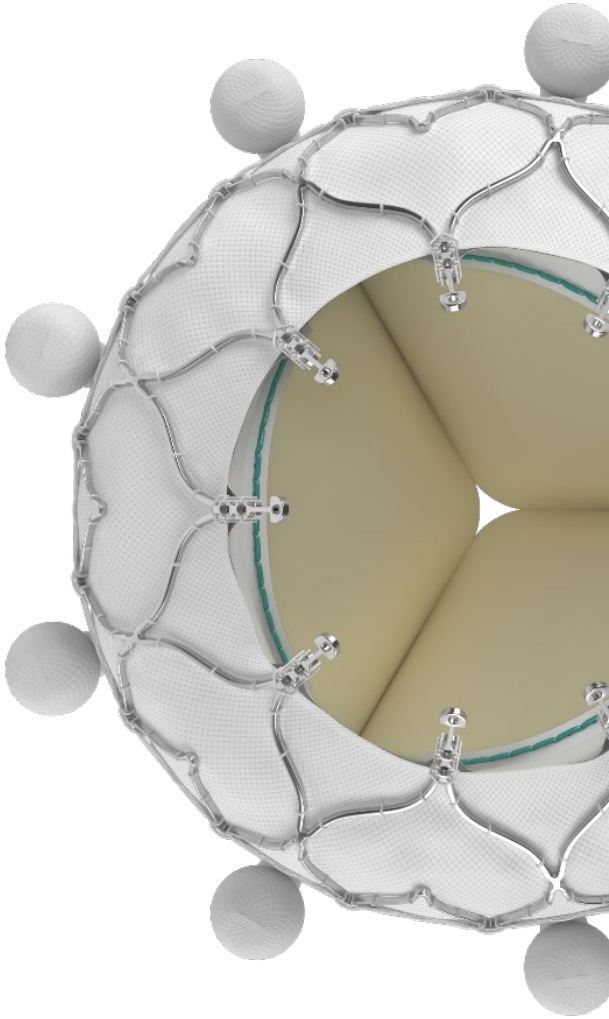
Procedure Step	Description
5	TEE and fluoroscopic guidance are used to monitor expansion of the bioprosthetic valve with nitinol frame, leaflet capture, and assure proper positioning throughout the deployment process.
6	After deployment and release of the bioprosthetic valve, the delivery catheter and guidewire are withdrawn across the valve and from the right atrium. The catheter is retracted and removed from the access site; venous access is closed.
7	Proper positioning and functioning of the bioprosthetic valve, including the assessment of any paravalvular leakage, is confirmed by TEE. Measurement of regurgitation and resultant gradient is assessed.

Identifying the EVOQUE System in the medical record

The Edwards EVOQUE tricuspid valve replacement system received FDA Breakthrough Device Designation on December 18, 2019, and received FDA approval on February 1, 2024 (P230013)

Documentation of the EVOQUE System will be included in the operative report and may be referred to as:

- Edwards EVOQUE tricuspid valve replacement system
- Edwards transcatheter tricuspid valve replacement system
- EVOQUE tricuspid valve replacement system
- Transcatheter tricuspid valve replacement
- Percutaneous tricuspid valve replacement
- EVOQUE
- EVOQUE system
- EVOQUE valve



Questions?