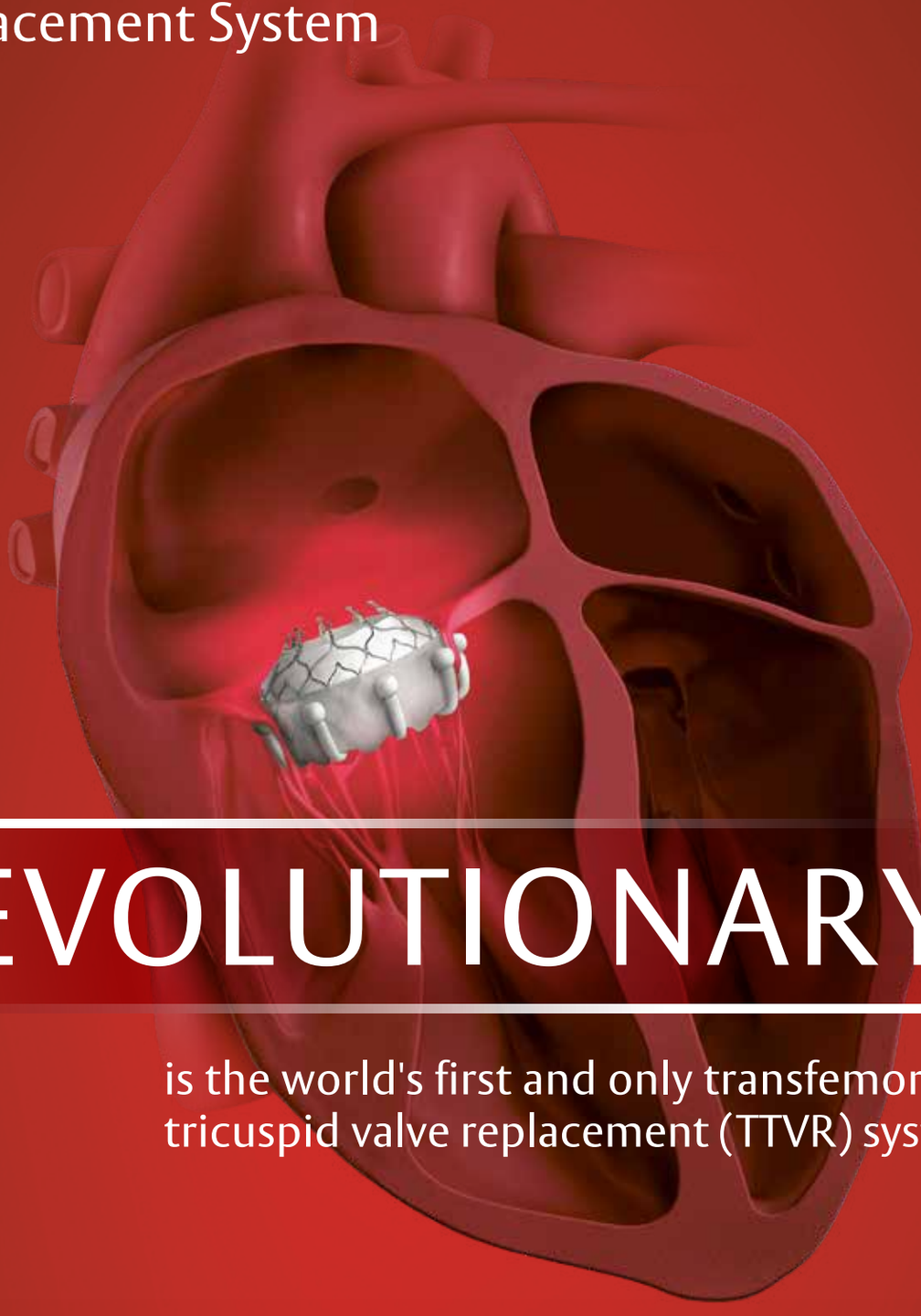
Edwards EVOQUE Tricuspid Valve Replacement System



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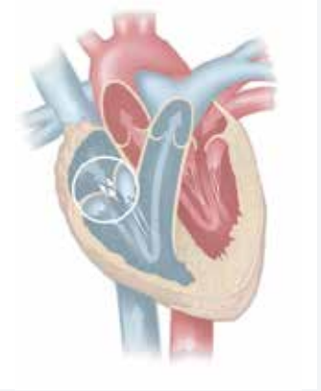
is the world's first and only transfemoral tricuspid valve replacement (TTVR) system

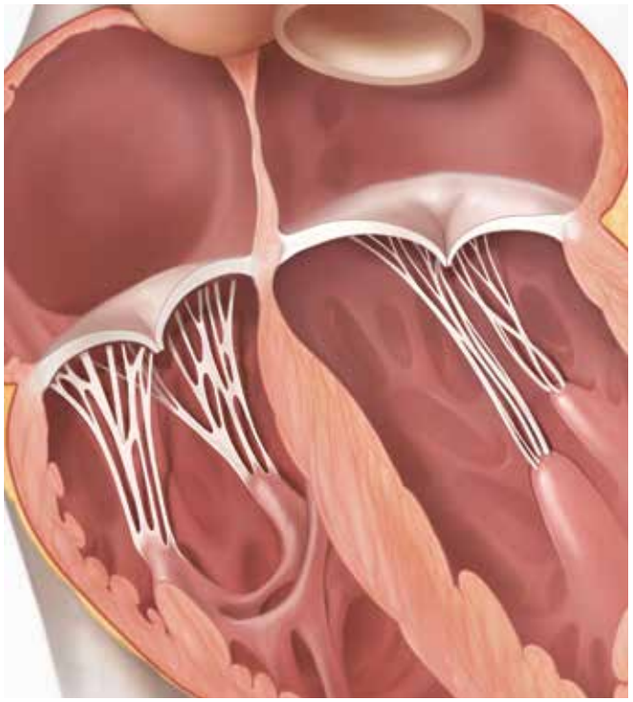
Edwards

Severe tricuspid regurgitation (TR) is often an undertreated life-threatening condition[1,2]

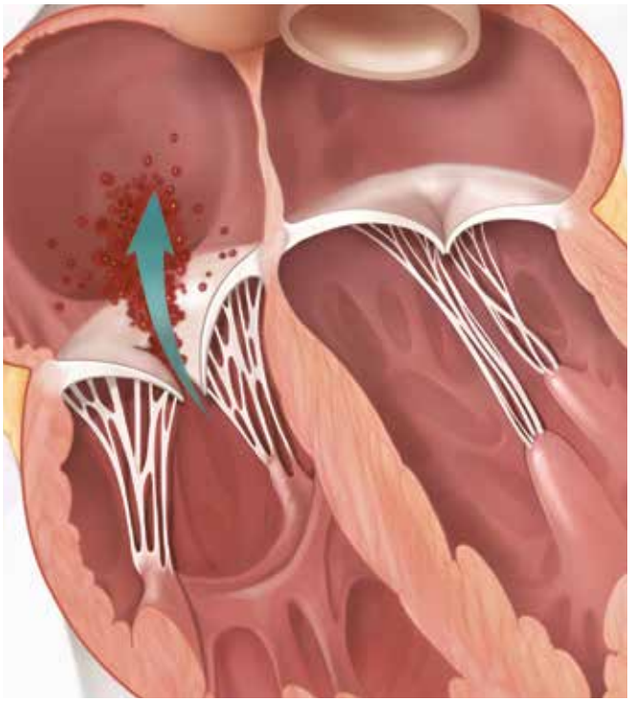
- TR occurs predominantly as a result of left-sided heart disease and increased left atrial pressure[3]
- Left-sided heart disease can lead to pulmonary hypertension, a subsequent rise in right ventricular (RV) pressure, and progressive RV dysfunction and dilatation[3]
- TR may be caused by atrial enlargement secondary to atrial fibrillation[3]



Healthy Tricuspid Valve



Heart with Tricuspid Regurgitation



DID YOU KNOW?

Medications, such as diuretics, may treat symptoms but not the TR itself, which can continue to progress[1,4]

TR and right heart failure may result in debilitating symptoms and poor outcomes when not adequately treated[1,5]

Progressive right ventricular (RV) dysfunction can result in morbidities, including:[1,5]

Edema

Ascites

Dyspnea

Chest Pain

TR can progress in severity[6]

Prevalence

2.6% of adults aged 65 or older were found to have moderate or greater TR[2,7*]

Over 1.5 million people in the United States are estimated to have clinically relevant TR[2,7,8]

Severity

~19% of patients with mild or trivial TR progressed to moderate or severe TR in about 3 years[9†]

Mortality

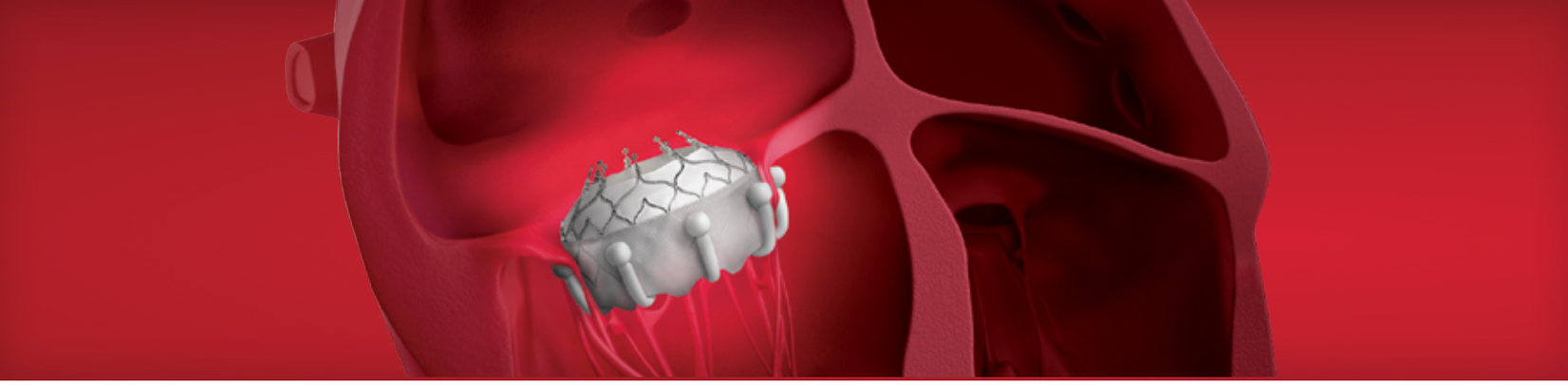
>20% estimated mortality in patients with severe TR within 1 year of diagnosis[10,11]

DID YOU KNOW?

Reducing TR severity may improve patient quality of life[1,12]

*Prospective observational study conducted in the UK, n=9,504

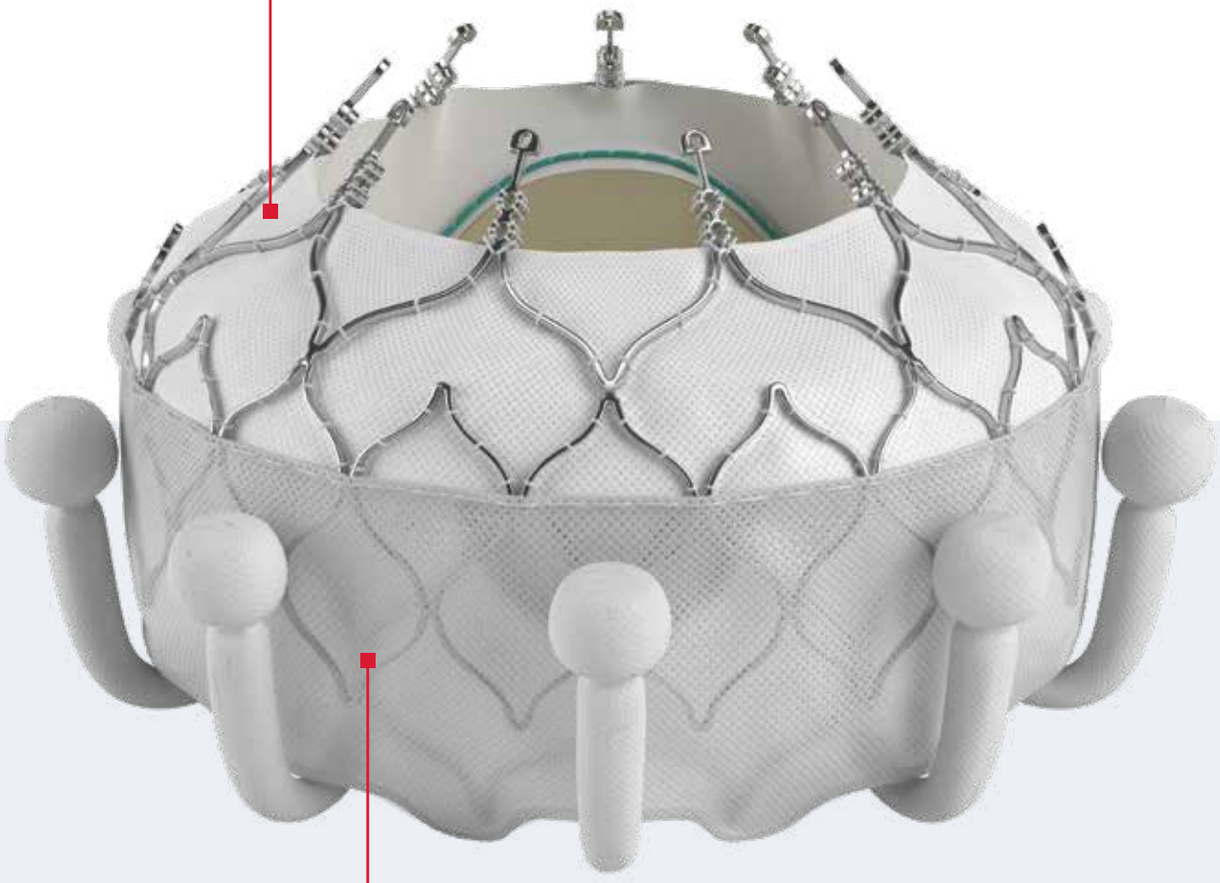
†Based on Israeli data, n=1,552



Learn about the EVOQUE valve

Designed for anatomical compatibility

Self-expanding, shape-memory nitinol frame designed to conform to native valve anatomy

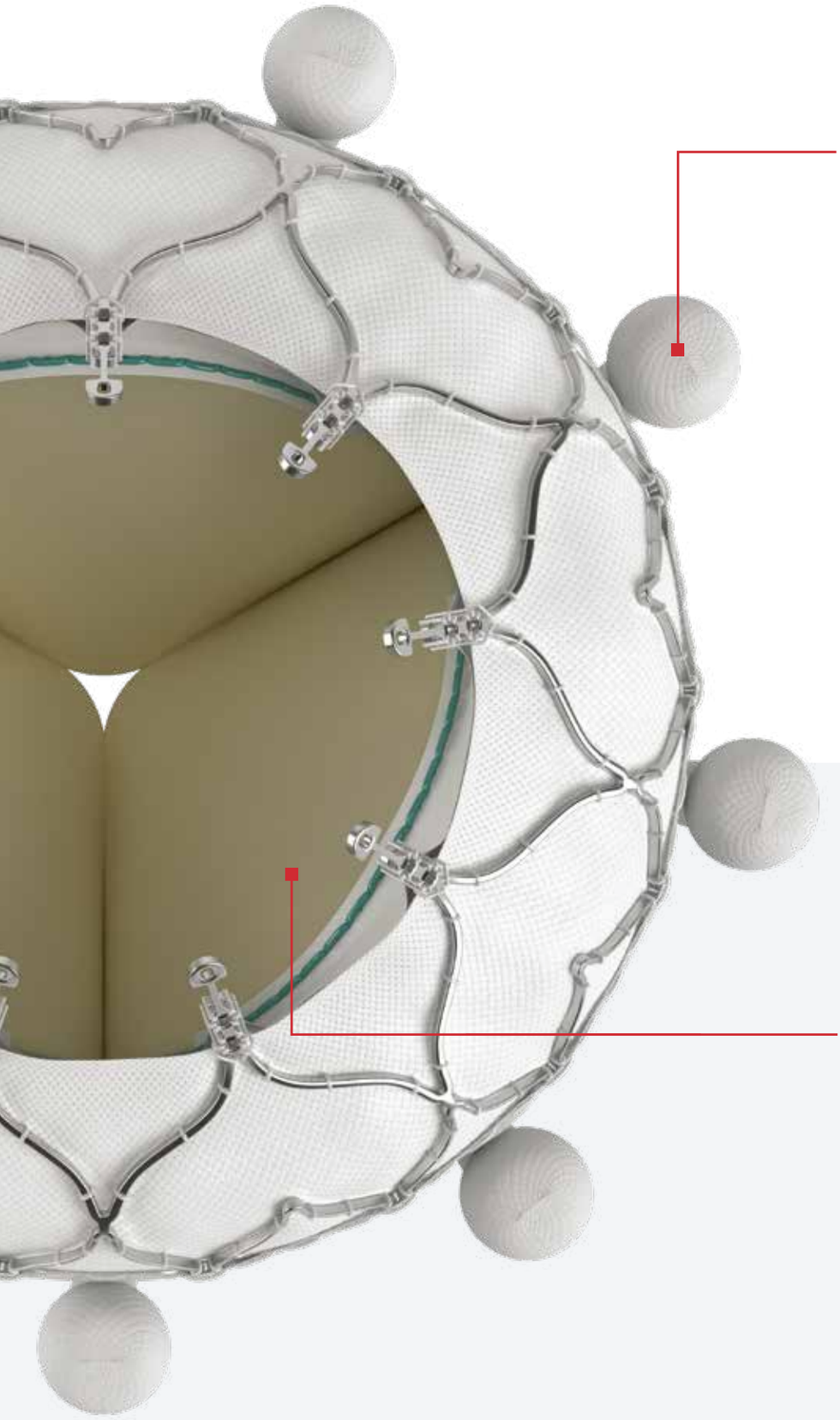


Designed to seal within the native tricuspid annulus

Intra-annular sealing skirt and frame

REVOLUTIONARY

is the world's first transcatheter tricuspid valve replacement system



Designed for a secure transcatheter implantation

Nine ventricular anchors engage leaflets, subvalvular anatomy and the annulus

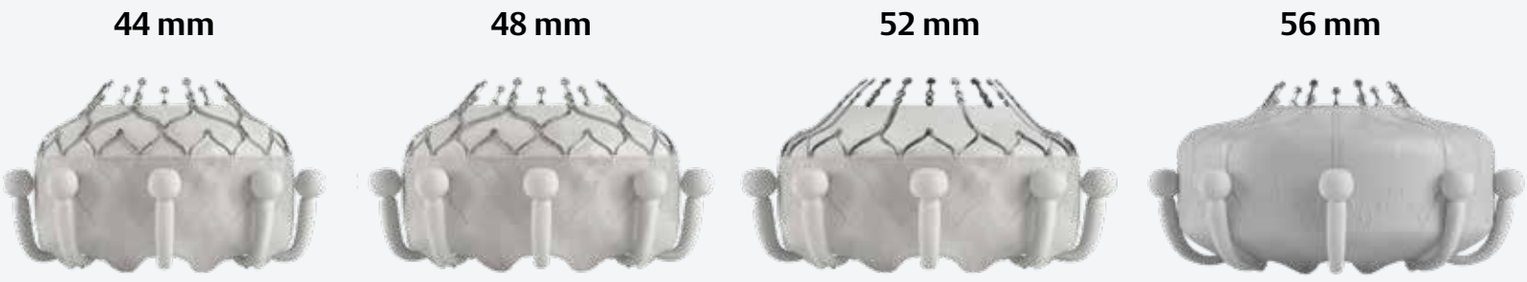
Made from Edwards' bovine pericardial tissue

Same bovine pericardial tissue as Edwards SAPIEN and PERIMOUNT valves †

† Excluding the SAPIEN 3 Ultra RESILIA valves

Designed with your patients in mind

Multiple valve sizes to treat a wide range of patient anatomies



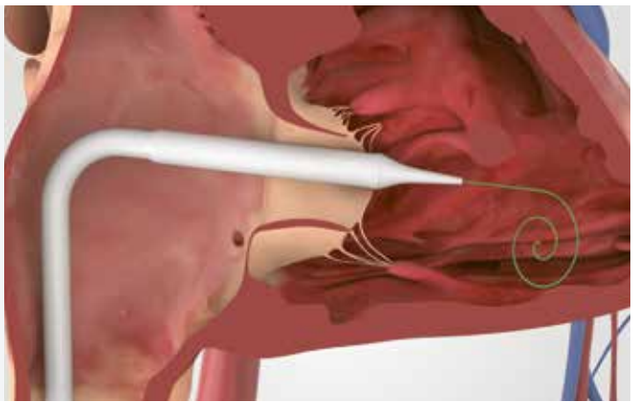
Transfemoral 28F outer diameter delivery system designed for maneuverability

EVOQUE stabilizer, base, and plate

A transcatheter system designed for ease of use

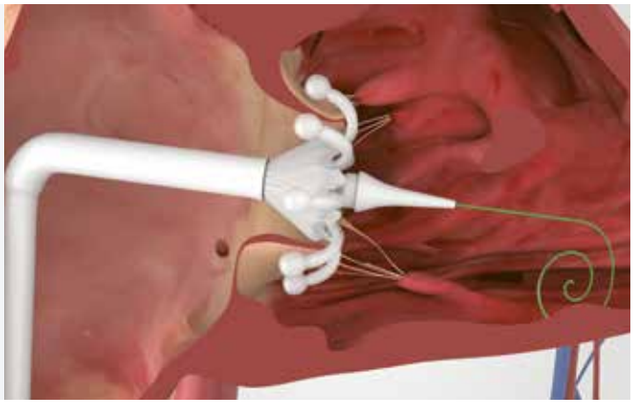
Access

Transfemoral 28F outer diameter delivery system with 3 planes of movement



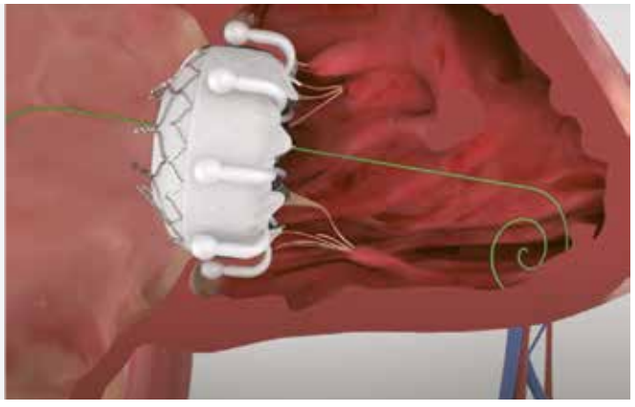
Position

Expose anchors to engage leaflets and the annulus



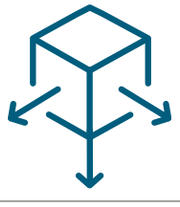
Deploy

Expand valve and gradually release system



DID YOU KNOW?

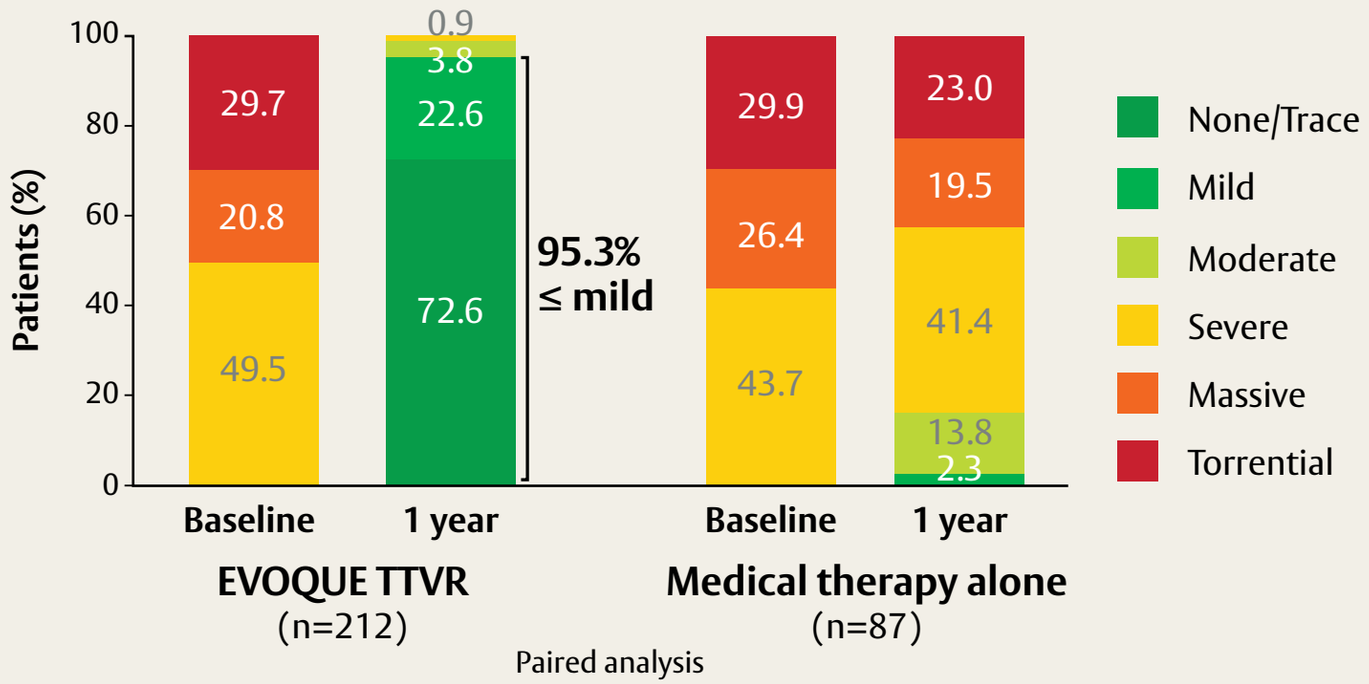
Low profile delivery system has 3 planes of movement designed for controlled positioning



The EVOQUE valve is the world's first and only transcatheter tricuspid valve replacement (TTVR) system

THE TRISCEND II PIVOTAL TRIAL

TTVR effectively eliminates TR in the majority of patients despite the presence of massive or torrential TR in >50% at baseline



99.1%

of patients achieved moderate or less TR with EVOQUE TTVR at 1 year

95.3%

of patients achieved mild or less TR with EVOQUE TTVR at 1 year

The EVOQUE valve provided clinically meaningful improvements in quality of life, functional status, and exercise capacity.

Greater magnitude of improvement at 1 year among patients treated with the EVOQUE valve + optimal medical therapy (OMT) compared to patients treated with OMT alone for:

- KCCQ score
- NYHA class
- 6-minute walk distance

Important Safety Information

Edwards EVOQUE Tricuspid Valve Replacement System

Indications: The EVOQUE tricuspid valve replacement system is indicated for the improvement of health status in patients with symptomatic severe tricuspid regurgitation despite being treated optimally with medical therapy for whom tricuspid valve replacement is deemed appropriate by a Heart Team.

Contraindications: The EVOQUE valve is contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen, who have active bacterial endocarditis or other active infections, or who have untreatable hypersensitivity to nitinol alloys (nickel and titanium).

Warnings: The EVOQUE valve, delivery system, loading system, dilator kit, are designed, intended, and distributed as STERILE and for single use only. The positioning accessories are available in single use, nonsterile, disposable as well as reusable configurations, please refer to the device information and ensure the device is used as intended. Do not resterilize or reuse any of the single use devices. There are no data to support the sterility, nonpyrogenicity, or functionality of the single use devices after reprocessing. Ensure the correct valve size is selected. Implantation of the improper size (i.e., undersizing or oversizing) may lead to paravalvular leak (PVL), migration, embolization, and/or annular damage.

Patients with previously-implanted devices (e.g., IVC filter) should be carefully assessed prior to insertion of the delivery system to avoid potential damage to vasculature or a previously-implanted device. Patients with pre-existing cardiac leads should be carefully assessed prior to implantation to avoid potential adverse interaction between devices. Care should be taken when implanting cardiac leads after EVOQUE valve implantation to avoid potential adverse interaction between the devices. Patients implanted with the EVOQUE valve should be maintained on anticoagulant/antiplatelet therapy as determined by their physicians in accordance with current guidelines, to minimize the risk of valve thrombosis or thromboembolic events.

There are no data to support device safety and performance if the patient has: echocardiographic evidence of severe right ventricular dysfunction; pulmonary arterial systolic pressure (PASP) > 70 mmHg by echo Doppler; a trans-tricuspid pacemaker or defibrillator lead that has been implanted in the RV within the last 3 months; or dependency on a trans-tricuspid pacemaker without alternative pacing options.

Precautions: Prior to use, the patient's eligibility depends on the anatomic conditions based on CT scan. It is advised that a multi-disciplinary heart team be of the opinion that EVOQUE valve implantation is preferable to alternative percutaneous device solutions, including minimally-invasive open heart surgery. It is advised that a multi-disciplinary heart team takes into consideration the severity of disease and the chances of reversibility of right heart failure based on a complete hemodynamic assessment.

The EVOQUE valve is to be used only with the EVOQUE delivery system and EVOQUE loading system. The procedure should be conducted under appropriate imaging modalities, such as transesophageal echocardiography (TEE), fluoroscopy, and/or intracardiac echocardiography (ICE). Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Safety Data Sheet available from Edwards Lifesciences. Conduction disturbances may occur before, during, or following implantation of the EVOQUE valve, which may require continuous ECG monitoring before hospital discharge. The risk of conduction disturbances may increase with the 56mm valve size. If a patient has confirmed or suspected conduction disturbances, consider patient monitoring and/or electrophysiology evaluation. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Long-term durability has not been established for the EVOQUE valve. Regular medical follow-up is advised to evaluate EVOQUE valve performance. Implantation of the EVOQUE valve should be postponed in patients with (1) a history of myocardial infarction within one month (30 days) of planned intervention, (2) pulmonary emboli within 3 months (90 days) of planned intervention, (3) cerebrovascular accident (stroke or TIA) within 3 months (90 days) of planned intervention, (4) active upper GI bleeding within 3 months (90 days) prior to procedure requiring transfusion.

Potential Adverse Events: Potential adverse events related to standard cardiac catheterization, use of anesthesia, the EVOQUE valve, and the implantation procedure include: death; abnormal lab values; allergic reaction to anesthesia, contrast media, anti-coagulation medication, or device materials; anaphylactic shock; anemia or decreased hemoglobin (Hgb), may require transfusion; aneurysm or pseudoaneurysm; angina or chest pain; arrhythmia – atrial (i.e., atrial fibrillation, supraventricular tachycardia); arrhythmias – ventricular (i.e., ventricular tachycardia, ventricular fibrillation); arterio-venous fistula; bleeding; cardiac arrest; cardiac (heart) failure; cardiac injury, including perforation; cardiac tamponade / pericardial effusion; cardiogenic shock; chordal entanglement or rupture that may require intervention; coagulopathy, coagulation disorder, bleeding diathesis; conduction system injury, which may require implantation of a pacemaker (temporary or permanent); conversion to open heart surgery; coronary artery occlusion; damage to or interference with function of pacemaker or implantable cardioverter defibrillator (ICD); edema; electrolyte imbalance; embolization including air, particulate, calcific material, or thrombus; emergent cardiac surgery; endocarditis; esophageal irritation; esophageal perforation or stricture; EVOQUE system component(s) embolization; failure to retrieve any EVOQUE system components; fever; gastrointestinal bleeding; hematoma; hemodynamic compromise; hemolysis / hemolytic anemia; hemorrhage requiring transfusion/surgery; hypertension; hypotension; inflammation; injury to the tricuspid apparatus including chordal damage, rupture, papillary muscle damage; local and systemic infection; mesenteric ischemia or bowel infarction; multi-system organ failure; myocardial infarction; nausea and/or vomiting; nerve injury; neurological symptoms, including dyskinesia, without diagnosis of TIA or stroke; non-emergent reoperation; pain; pannus formation; paralysis; percutaneous valve intervention; peripheral ischemia; permanent disability; pleural effusion; pneumonia; pulmonary edema; pulmonary embolism; reaction to anti-platelet or anticoagulation agents; rehospitalization; renal failure; respiratory failure, atelectasis – may require prolonged intubation; retroperitoneal bleed; right ventricular outflow tract (RVOT) obstruction; septicemia, sepsis; skin burn, injury, or tissue changes due to exposure to ionizing radiation; stroke; structural deterioration (wear, fracture, calcification, leaflet tear, leaflet thickening, stenosis of implanted device, or new leaflet motion disorder); thromboembolism; transient ischemic attack (TIA); valve dislodgement/embolization; valve endocarditis; valve explant; valve leaflet entrapment; valve malposition; valve migration; valve paravalvular leak (PVL); valve regurgitation (new or worsening tricuspid, aortic, mitral, pulmonary); valve thrombosis; vascular injury or trauma, including dissection or occlusion; vessel spasm ; wound dehiscence, delayed or incomplete healing.

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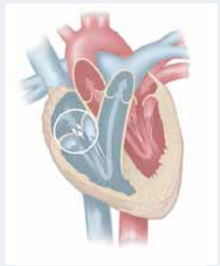

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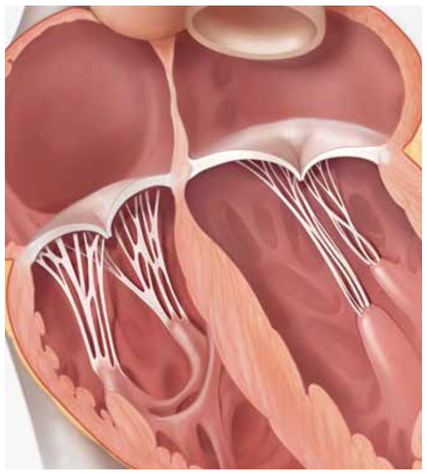
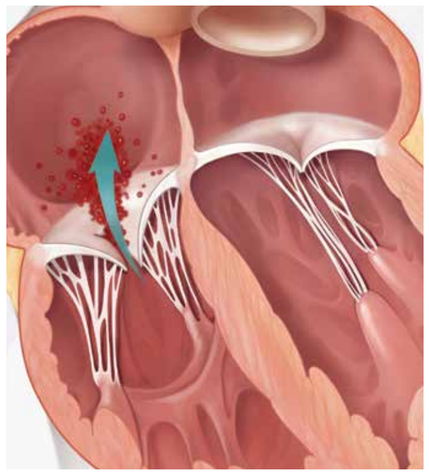


Heart with Tricuspid Regurgitation



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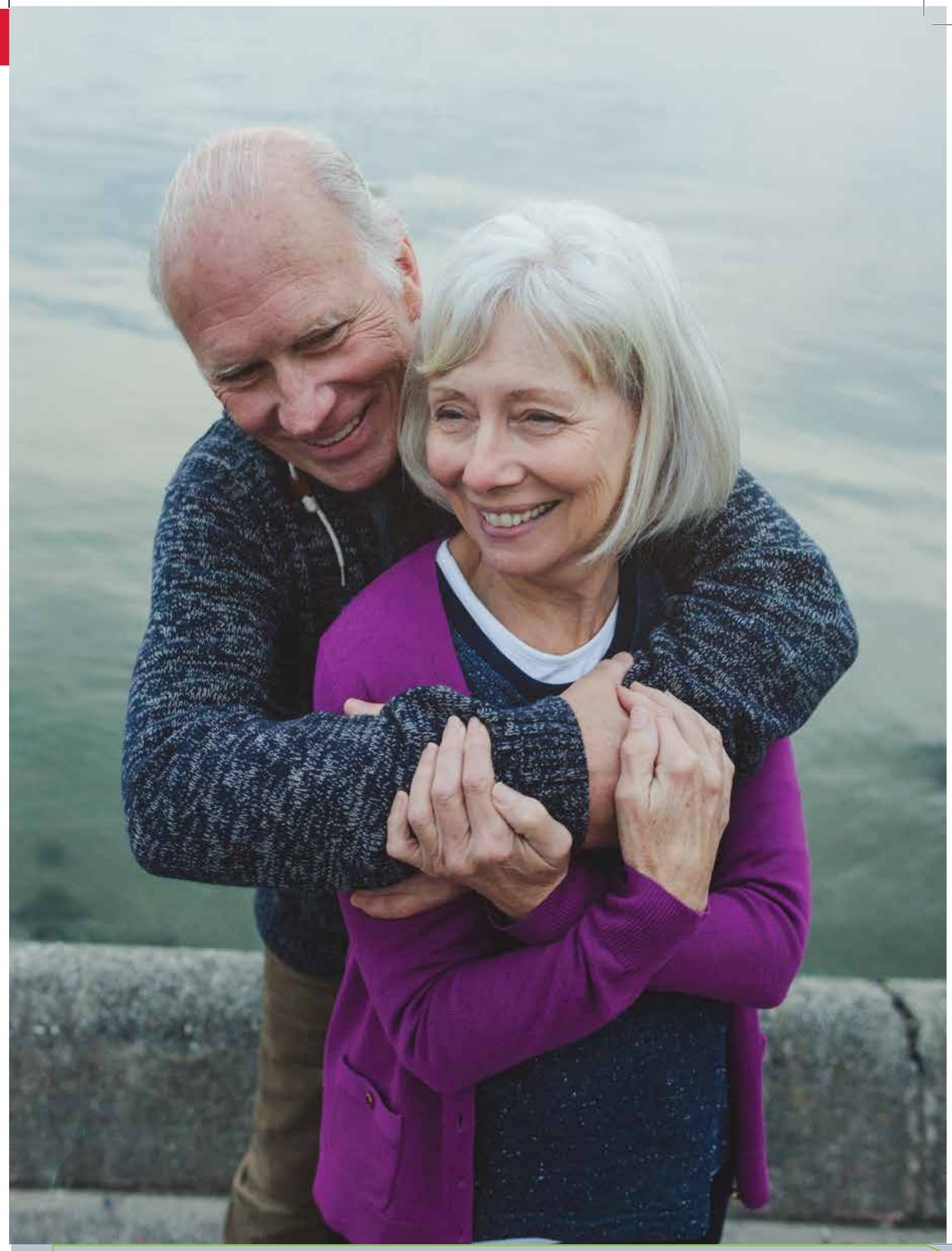

With the EVOQUE valve, you can experience

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Learn more at
Edwards.com/EVOQUE

References:

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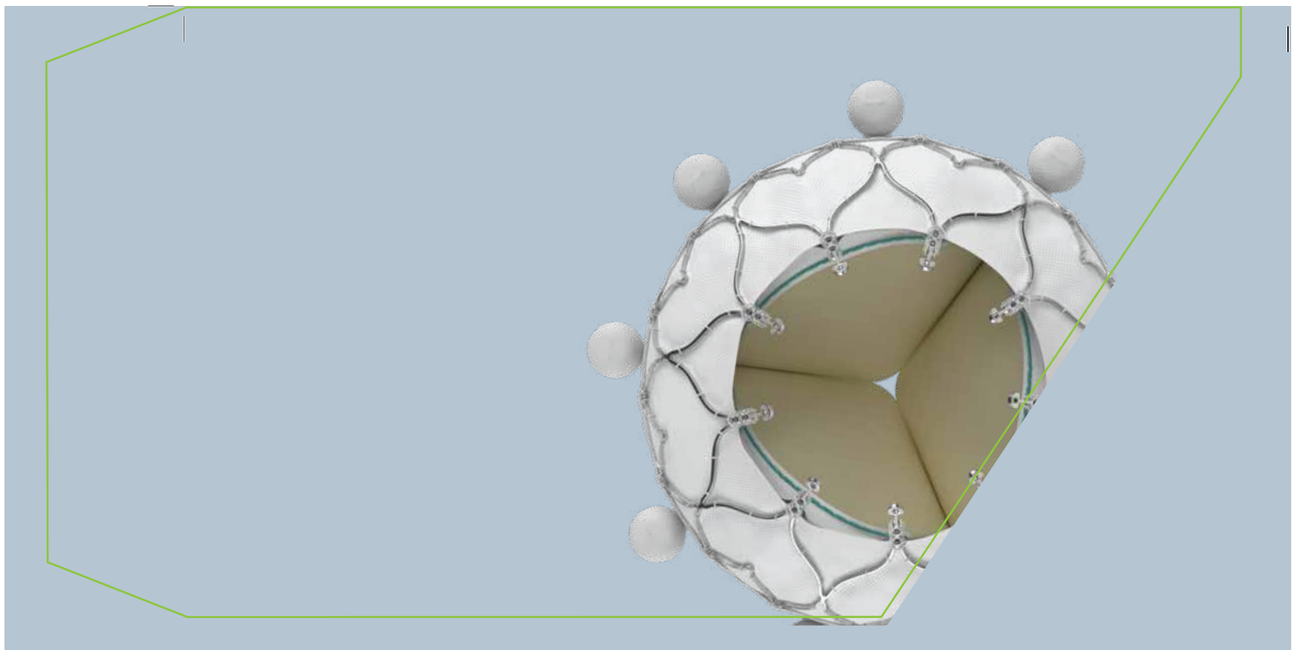

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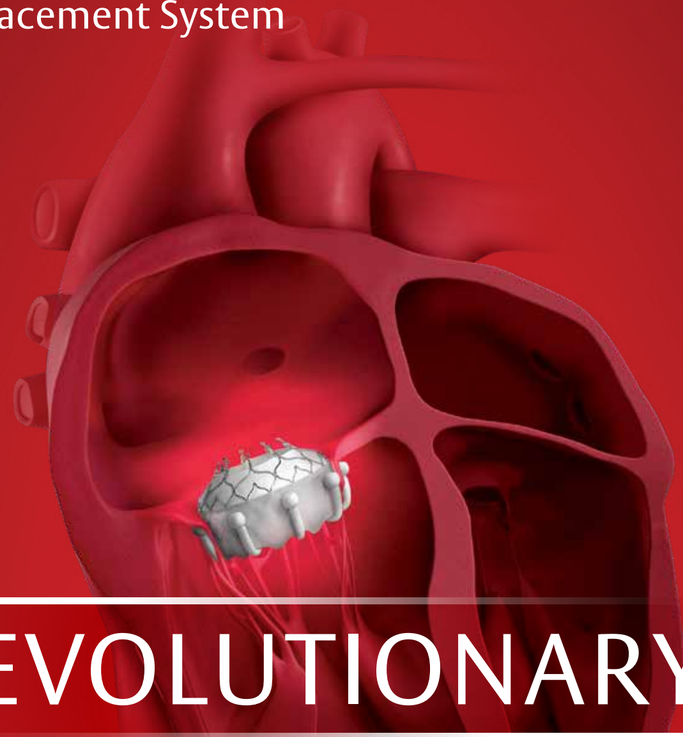

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