

Edwards EVOQUE
Tricuspid Valve
Replacement System



REVOLUTIONARY

is the first transfemoral tricuspid
valve replacement (TTVR) system*

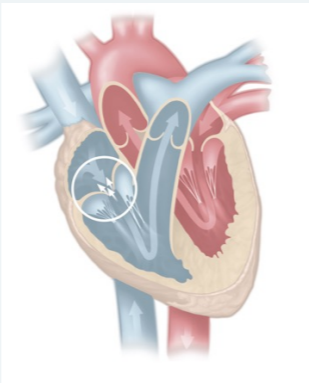
*First-of-its-kind device commercially available (in the EU).



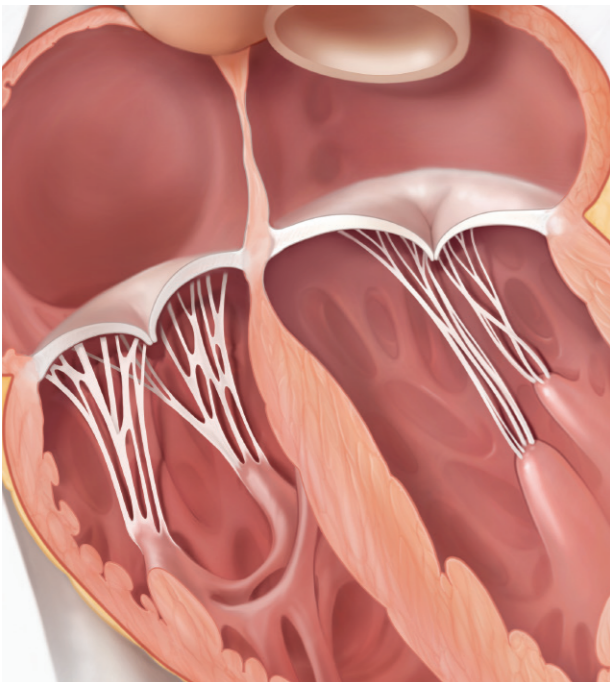
Edwards

Severe tricuspid regurgitation (TR) is often an undertreated life-threatening condition^{1,2*}

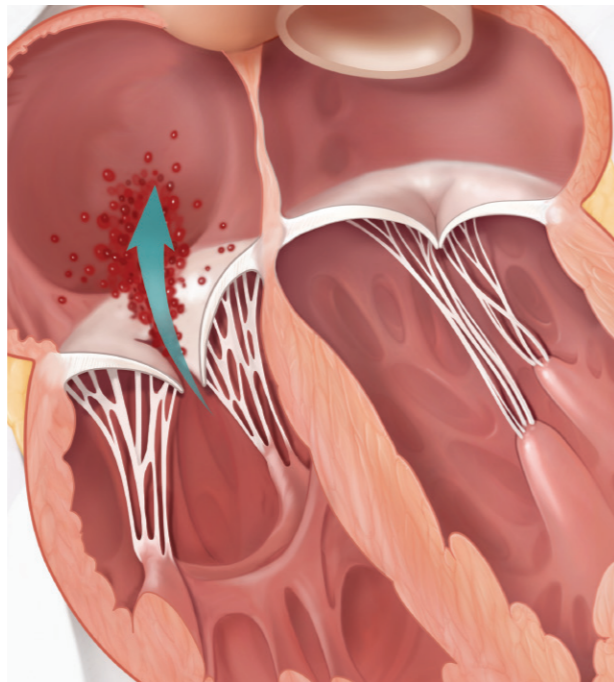
- TR occurs predominantly as a result of left-sided heart disease and increased left atrial pressure³
- Left-sided heart disease can lead to pulmonary hypertension, a subsequent rise in right ventricular (RV) pressure, and progressive RV dysfunction and dilatation³
- TR can be caused by atrial enlargement secondary to atrial fibrillation³



Healthy Tricuspid Valve



Heart with Tricuspid Regurgitation



TR and right heart failure may result in debilitating symptoms and poor outcomes when not adequately treated^{1,5}

Progressive right ventricular (RV) dysfunction or right atrial dilatation can lead to the development of right heart failure, which can result in morbidities including:^{1,6,7}

 Oedema	 Ascites
 Dyspnoea	 Fatigue

TR can progress in severity^{1,8}

Prevalence

2.6% of adults aged 65 or older were found to have moderate or greater TR^{9*}
Over 3 million people in Europe have clinically relevant TR¹⁰

Severity

19% of patients with mild or trivial TR progressed to moderate or severe TR in about 3 years^{11†}

Mortality

>20% of patients with severe TR are estimated to die within 1 year of diagnosis^{12,13}

DID YOU KNOW?

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



DID YOU KNOW?

Reducing TR severity may improve patient quality of life^{1,8}



*Based on US data.

[†]Based on a retrospective echocardiographic analysis of Israeli patients.

With the EVOQUE valve,

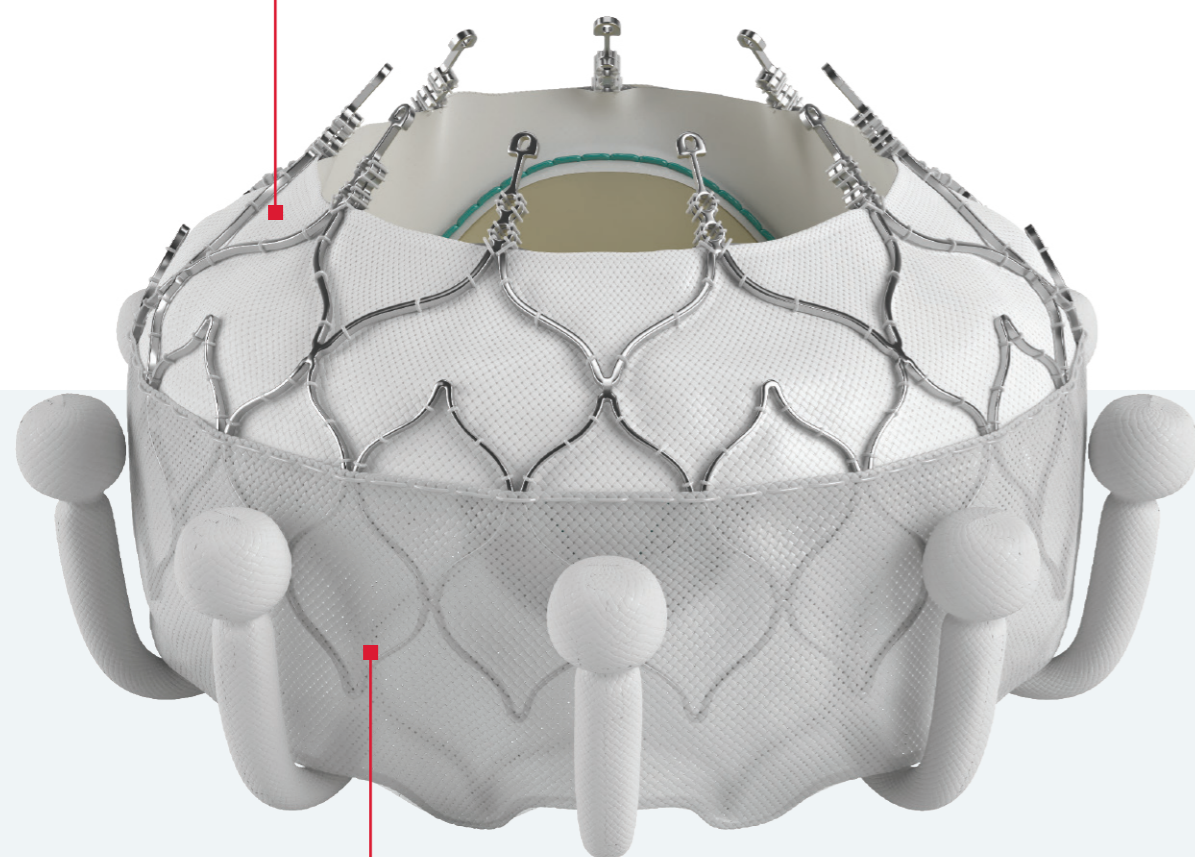
REVOLUTIONARY

is a first-of-its-kind transcatheter tricuspid valve option for eligible patients*

Introducing the EVOQUE valve

Designed for anatomical compatibility

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

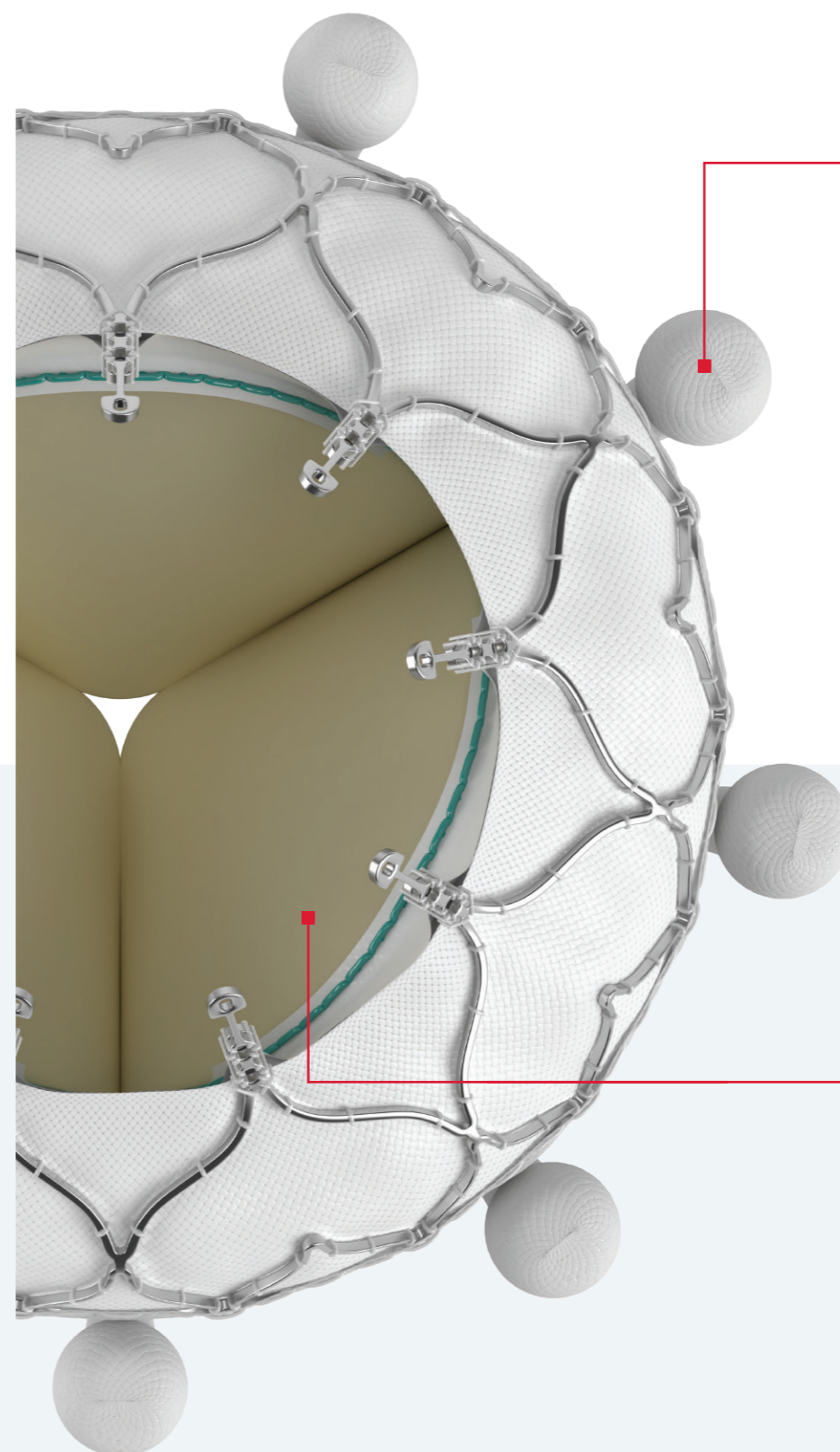


Designed to seal within the native tricuspid annulus

Intra-annular sealing skirt and frame

Designed for a secure transcatheter implantation

Nine ventricular anchors engage leaflets, subvalvular anatomy and the annulus.



ThermaFix tissue technology†

Same bovine pericardial tissue as Edwards SAPIEN and PERIMOUNT valves‡

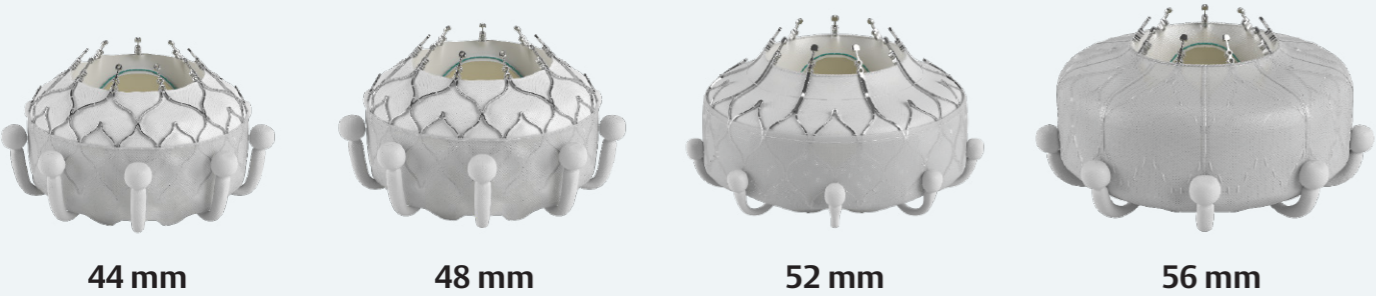
* First-of-its-kind device commercially available (in the EU).

† No clinical data are available that evaluate the long-term impact of the Carpentier-Edwards ThermaFix tissue process in patients.

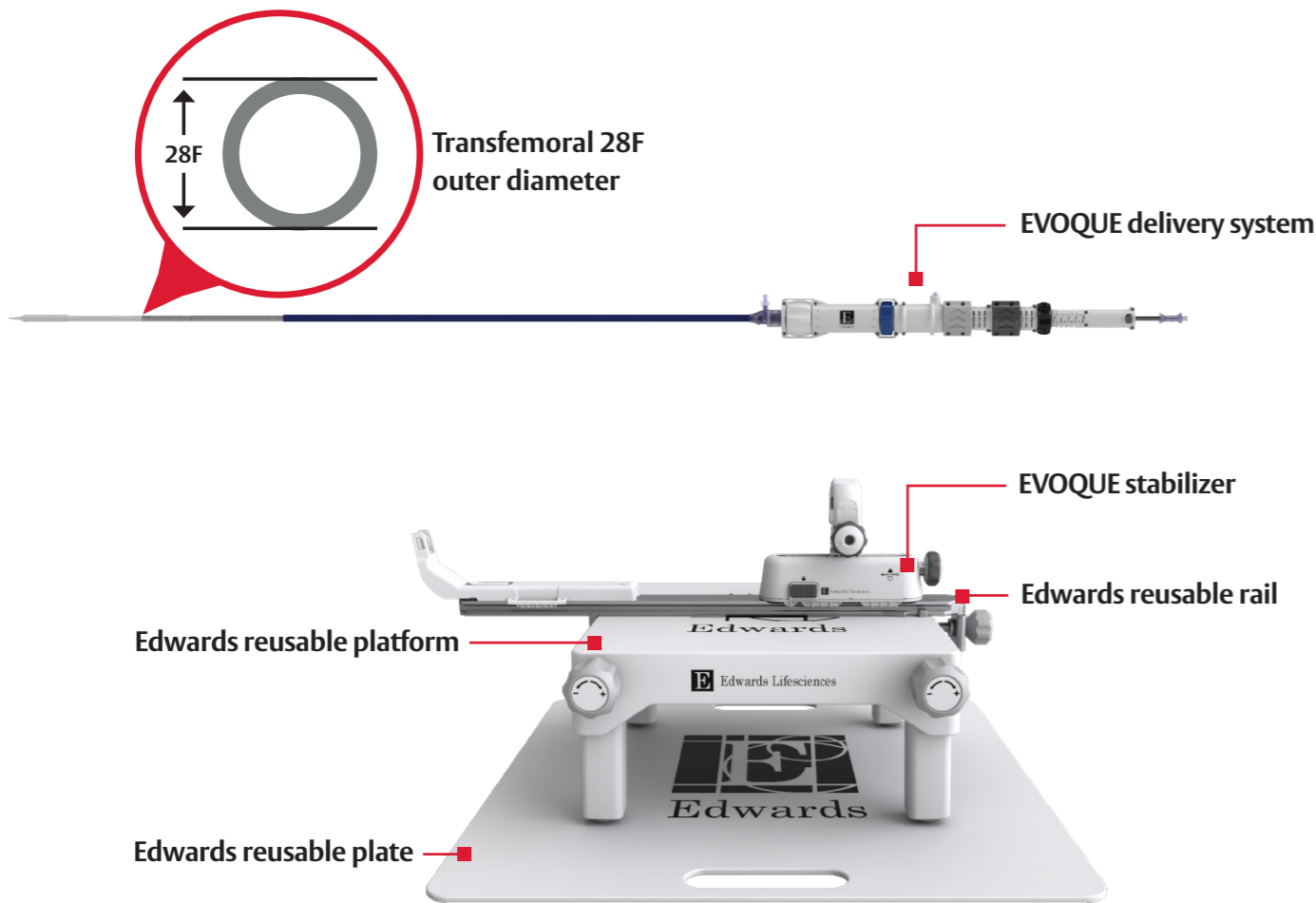
‡ Excluding Edwards SAPIEN 3 Ultra RESILIA valve

A system designed with your patients in mind

Multiple valve sizes designed to treat a wide range of tricuspid anatomies



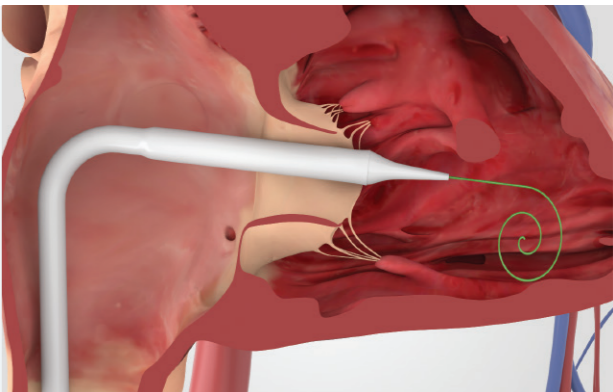
Transfemoral 28F outer diameter delivery system designed for manoeuvrability



A transcatheter procedure designed for ease of use¹⁴

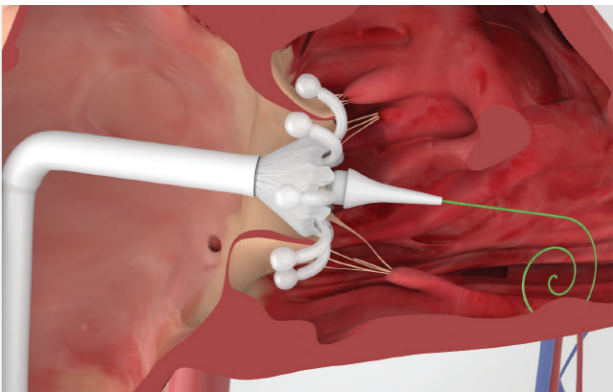
Access

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



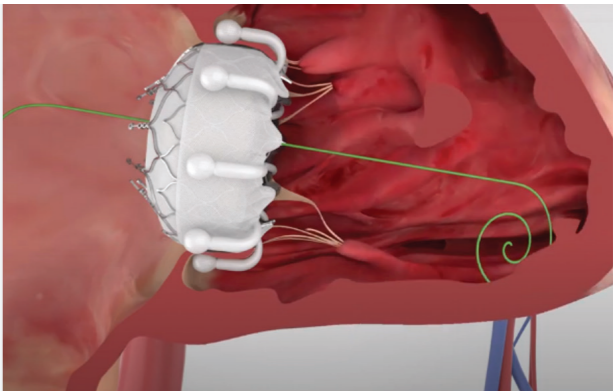
Position

Expose anchors to engage leaflets and the annulus



Deploy

Expand valve and gradually release system



DID YOU KNOW?

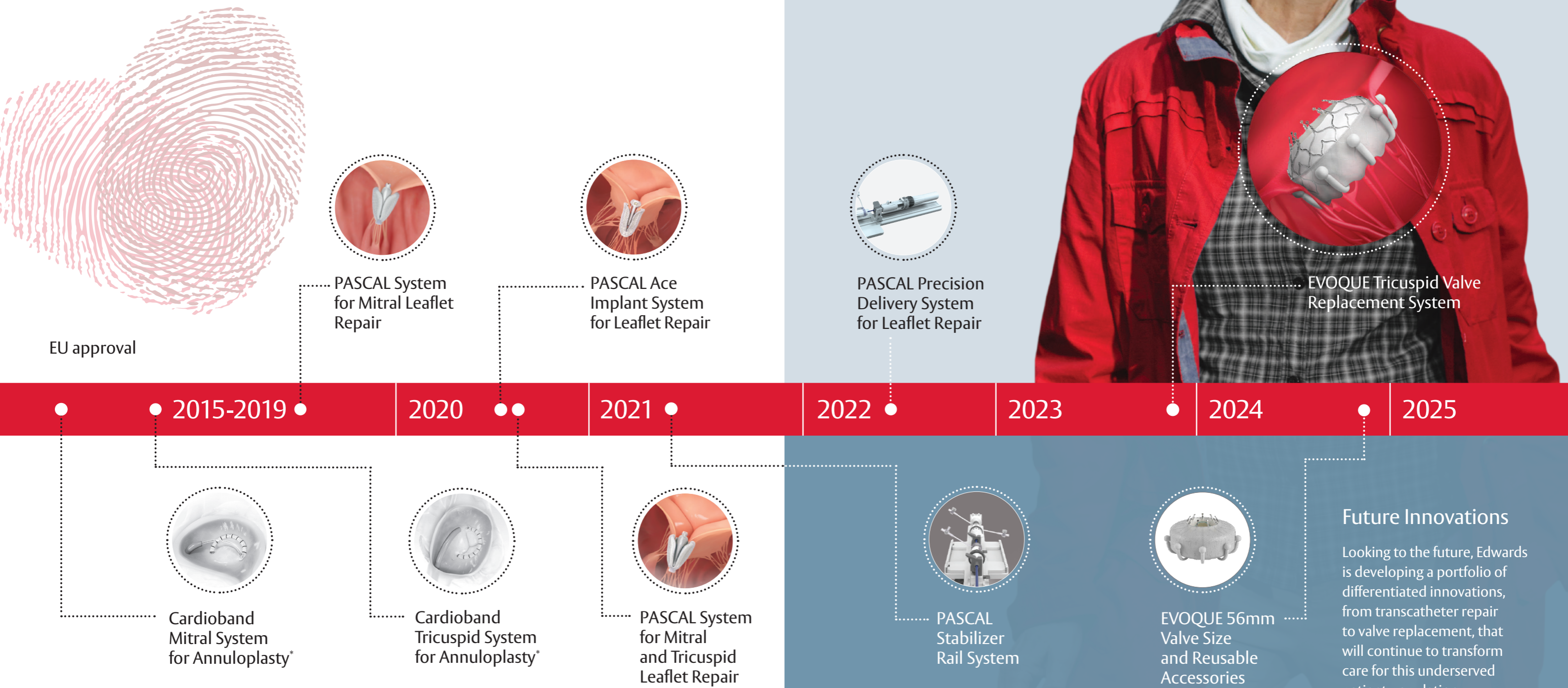
Low profile delivery system has 3 planes of movement designed for controlled positioning



Beyond the EVOQUE valve – Our portfolio of solutions for your patients

Making a mark in transcatheter mitral and tricuspid therapies

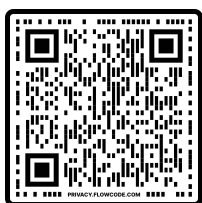
With solutions for valve replacement, leaflet repair, and annuloplasty, Edwards has the world’s broadest portfolio of transcatheter solutions that will help you Make a Mark in your patients’ lives.



*Cardioband has been discontinued and it is not available for commercial use

With the EVOQUE valve, you can experience

REVOLUTIONARY



Learn more at
Edwards.com/ca-en/EVOQUE

References:

1. Fender EA, Zack CJ, Nishimura RA. Isolated tricuspid regurgitation: Outcomes and therapeutic interventions. *Heart*. 2018;104(10):798-806.
2. Topilsky Y, Nkomo VT, Vatury O, et al. Clinical outcome of isolated tricuspid regurgitation. *JACC Cardiovasc Imaging*. 2014;7(12):1185-1194.
3. Mangieri A, Montalto C, Pagnesi M, et al. Mechanism and implications of the tricuspid regurgitation: From the pathophysiology to the current and future therapeutic options. *Circ Cardiovasc Interv*. 2017;10(7):1-12.
4. McDonagh TA, Metra M, Adamo M, et al. 2021 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur Heart J*. 2021;42(36):3599-3726.
5. Vahanian A, Beyersdorf F, Praz F, et al. 2021 ESC/EACTS guidelines for the management of valvular heart disease. *Eur Heart J*. 2022;43(7):561-632.
6. Benfari G, Antoine C, Miller WL, et al. Excess mortality associated with functional tricuspid regurgitation complicating heart failure with reduced ejection fraction. *Circ*. 2019;140(7):196-206.
7. Sisinni A, Taramasso M, Praz F, et al. Concomitant Transcatheter Edge-to-Edge Treatment of Secondary Tricuspid and Mitral Regurgitation. *Am Coll Cardiol Interv*. 2023;16:127-139.
8. Kelly BJ, Ho Luxford JM, Butler CG, et al. Severity of tricuspid regurgitation is associated with long-term mortality. *J Thorac Cardiovasc Surg*. 2018;155(3):1032-1038.
9. Cahill TJ, Prothero A, Wilson J, et al. Community prevalence, mechanisms and outcome of mitral or tricuspid regurgitation. *Heart*. 2021;107(12):1003-1009.
10. Nickenig G, Weber M, Schueler R, et al. 6-month outcomes of tricuspid valve reconstruction for patients with severe tricuspid regurgitation. *J Am Coll Cardiol*. 2019;73(15):1905-1915.
11. Mutlak D, Khalil J, Lessick J, Kehat I, Agmon Y, Aronson D. Risk factors for the development of functional tricuspid regurgitation and their population-attributable fractions. *JACC Cardiovasc Imaging*. 2020;13(8):1643-1651.
12. Chorin E, Rozenbaum Z, Topilsky Y, et al. Tricuspid regurgitation and long-term clinical outcomes. *Eur Heart J Cardiovasc Imaging*. 2020;21(2):157-165.
13. Messika-Zeitoun D, Verta P, Gregson J, et al. Impact of tricuspid regurgitation on survival in patients with heart failure: A large electronic health record patient-level database analysis. *Eur J Heart Fail*. 2020;22(10):1803-1813.
14. Kodali S, Hahn RT, George I, et al. Transfemoral tricuspid valve replacement in patients with tricuspid regurgitation: TRISCEND study 30-day results. *JACC Cardiovasc Interv*. 2022;15(5):471-480.

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