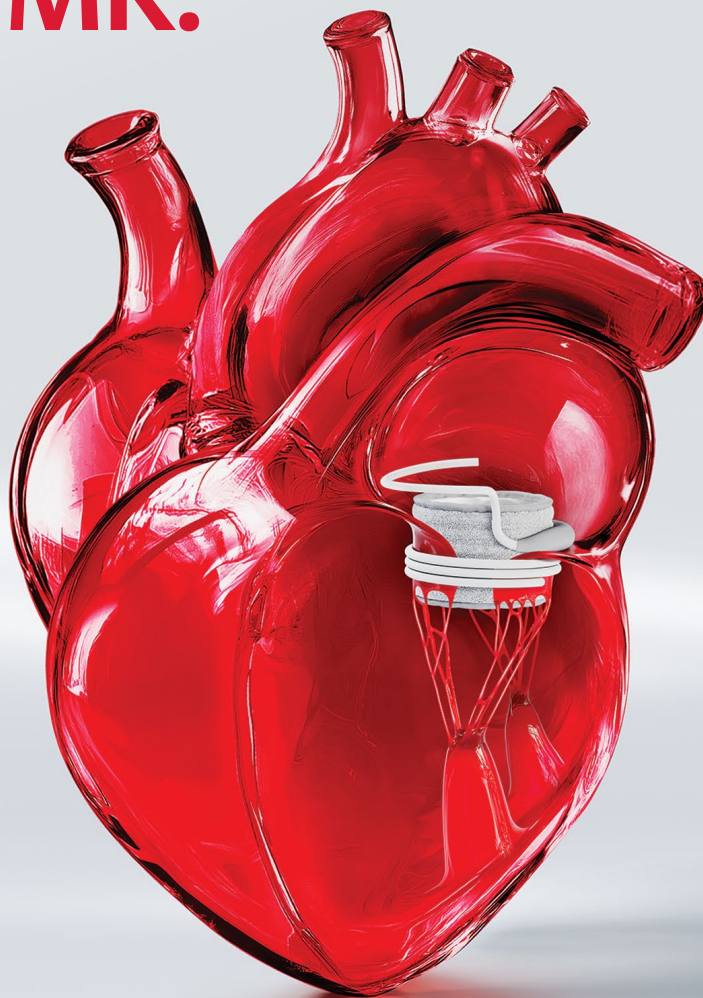


SAPIEN M3 System for TMVR

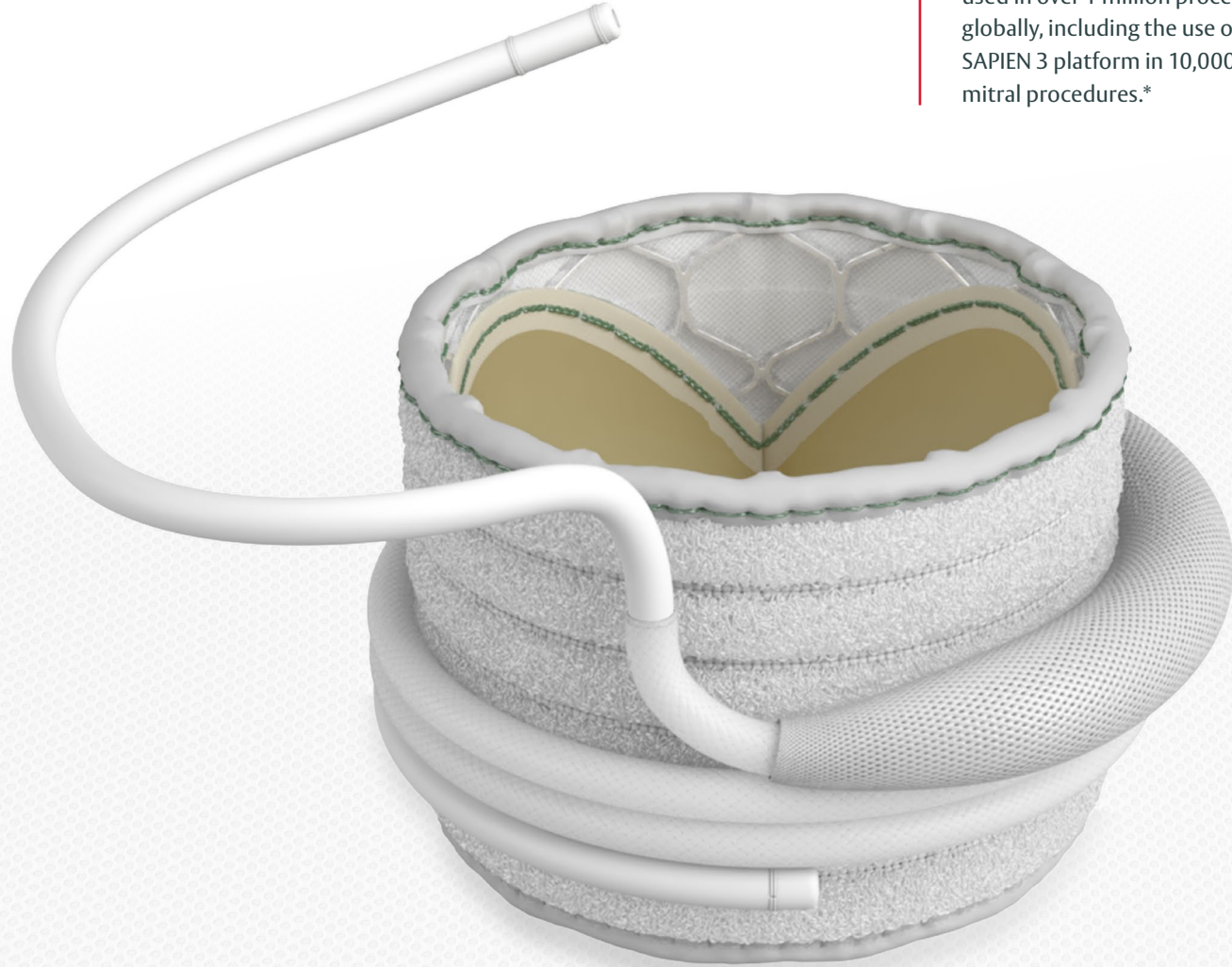
Touch more lives. Treat more MR.



The first and only approved fully transseptal approach to mitral valve replacement. Built on proven SAPIEN technology, designed to treat mitral regurgitation.



Edwards



A legacy of success

The SAPIEN platform has been used in over 1 million procedures globally, including the use of the SAPIEN 3 platform in 10,000+ mitral procedures.*

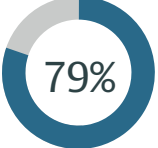
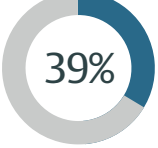
The latest evolution of SAPIEN technology, designed to treat the mitral valve

Treat more MR with the SAPIEN M3 system for patients with symptomatic moderate-to-severe or severe MR or symptomatic MAC-associated mitral valve dysfunction, including MR and/or MS, who are unsuitable for surgery or TEER.†

TMVR, transcatheter mitral valve replacement; MAC, mitral annular calcification; MR, mitral regurgitation; MS, mitral stenosis; TEER, transcatheter edge-to-edge repair.
*As of Q3 2025.
†MAC-associated mitral valve dysfunction includes moderate-to-severe or severe MR, severe MS, or moderate MR with moderate MS. See the Instructions for Use (IFU) for full indications.

The opportunity to advance mitral regurgitation care

MR contributes to the overall disease burden of heart failure and represents a major patient and societal burden.^{1, 2, 3, 4}

 MR affects approximately one in ten adults over 75 years^{5, 6}	 of patients with isolated moderate-to-severe MR and a Class I surgical indication go untreated^{*7}
 Approximately two-thirds of MR patients were readmitted at least once^{†4}	 of MR patients presented with heart failure^{†4}
 MR represented an extrapolated annual cost of 350–550M euros^{†4}	 mortality rate for non-operated patients with severe MR at 5 years⁸

Clinically relevant MR is associated with a poor quality of life and may include symptoms like: ^{1, 9, 10}



shortness of breath



feeling fatigued



swelling of hands and feet



heart palpitations

* Based on US data.

† In a nation-wide study in France.

1 Lim DS, et al. *Am J Cardiol.* 2014; 2 Kaneko H, et al. *Heart Vessels.* 2013; 3 Stolfo D, et al. *Am J Cardiol.* 2015; 4 Messika-Zeitoun D, et al. *Am Heart J.* 2020; 5 Nkomo VT, et al. *Lancet.* 2006; 6 Praz F, et al. *Swiss Med Wkly.* 2019; 7 Dziadzko V, et al. *Lancet.* 2018; 8 Goel SS, et al. *Am J Cardiol.* 2013; 9 Mitral Valve Regurgitation. Penn Medicine. Accessed November 20, 2024. <https://www.pennmedicine.org/for-patients-and-visitors/patient-information/conditions-treated-a-to-z/mitral-valve-regurgitation>; 10 Sodhi N. Transcatheter Treatment of Functional Mitral Regurgitation in Patients with Heart Failure: The COAPT Trial. Elsevier Health Sciences; 2020:451-459.

One system. Two parts. MR treatment reimaged.

The SAPIEN M3 transcatheter mitral valve replacement (TMVR) system significantly reduces mitral regurgitation.¹¹

SAPIEN M3 Dock

Encircles and captures the native mitral leaflets to create a stable and standardized landing zone for the SAPIEN M3 valve

Radiopaque markers

to visualize proper positioning and deployment within the anatomy

Nitinol PVL guard

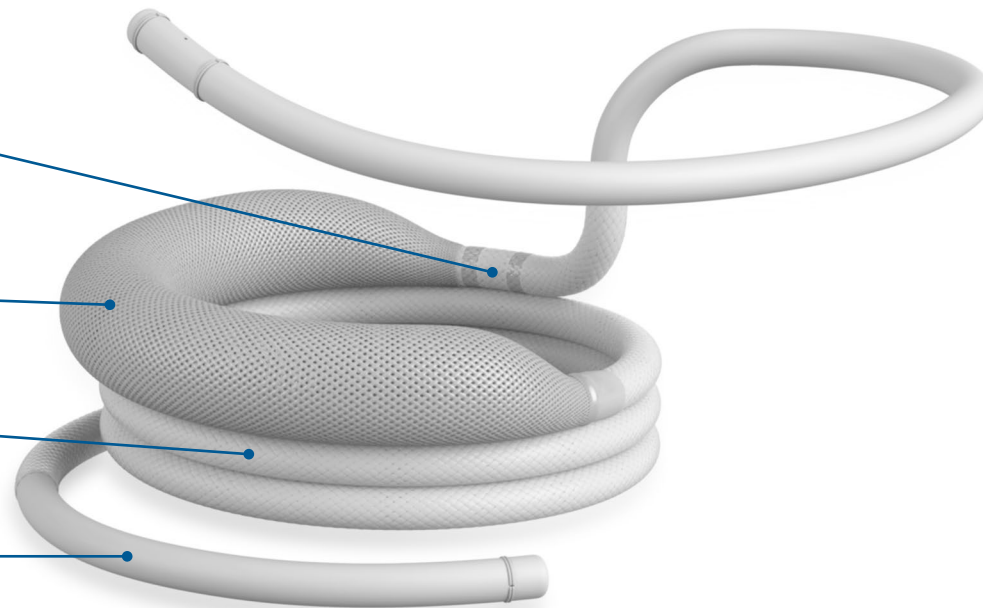
expands in the medial commissure

Functional turns

provide a stable anchor for the SAPIEN M3 valve

Encircling turn

captures the native mitral leaflets



SAPIEN M3 Valve

Built on the proven SAPIEN technology, optimized to treat mitral regurgitation

Cobalt-chromium alloy frame

provides radial strength and good visibility under fluoroscopy

Trileaflet bovine pericardial tissue

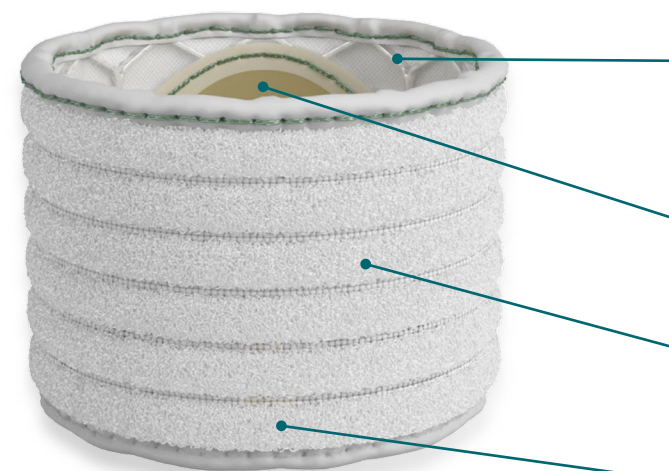
treated with the TheraFix tissue process

Full-frame PET skirt

respects the native anatomy

Single 29mm valve

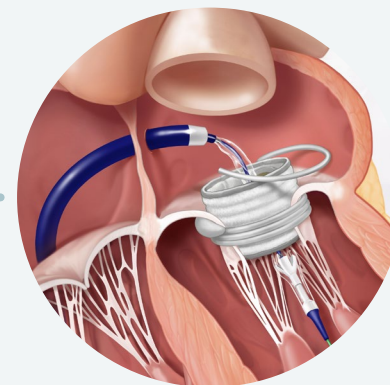
can treat a variety of mitral anatomies



Transseptal access The low-profile Edwards 23F inner diameter guide sheath is used for both the dock and valve delivery, providing a minimally invasive transseptal approach to TMVR.¹²



Dock delivery The SAPIEN M3 dock steerable catheter enables responsive navigation and positioning of the dock. The dock is repositionable and retrievable prior to dock release.



Valve delivery The Edwards Commander M delivery system uses on-balloon valve crimping and allows accurate valve positioning for controlled deployment.



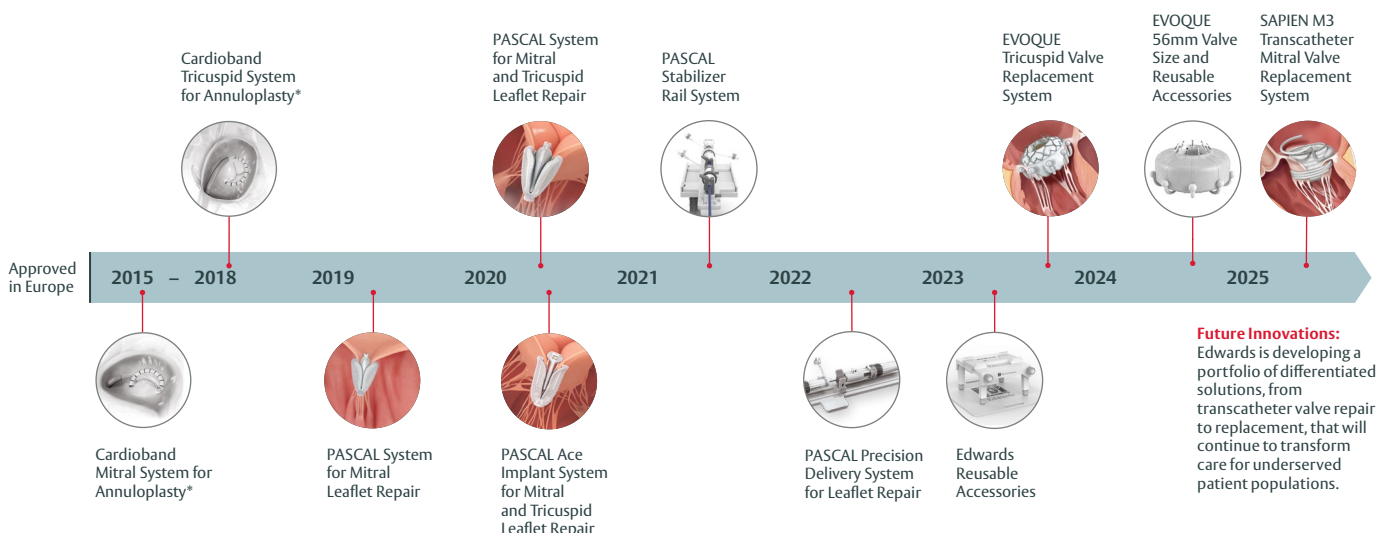
Final implant The SAPIEN M3 system delivers significant MR reduction with proven safety profile and meaningful health status improvements.¹¹

PET, polyethylene terephthalate.

¹¹ Guerrero M, et al. *Lancet*. 2025; 12 Transcatheter Mitral Valve Replacement (TMVR). Penn Medicine. Accessed January 6, 2025. <https://www.pennmedicine.org/for-patients-and-visitors/find-a-program-or-service/heart-and-vascular/heart-valve-disease/treatments-and-procedures/transcatheter-mitral-valve-replacement>

Producing a steady beat of innovation

Edwards is committed to advancing transcatheter mitral and tricuspid therapies.



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



Learn more about the SAPIEN M3 system
at [Edwards.com/gb/SAPIENM3](https://www.edwards.com/gb/SAPIENM3)

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Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult [eifu.edwards.com](https://www.edwards.com) where applicable).

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