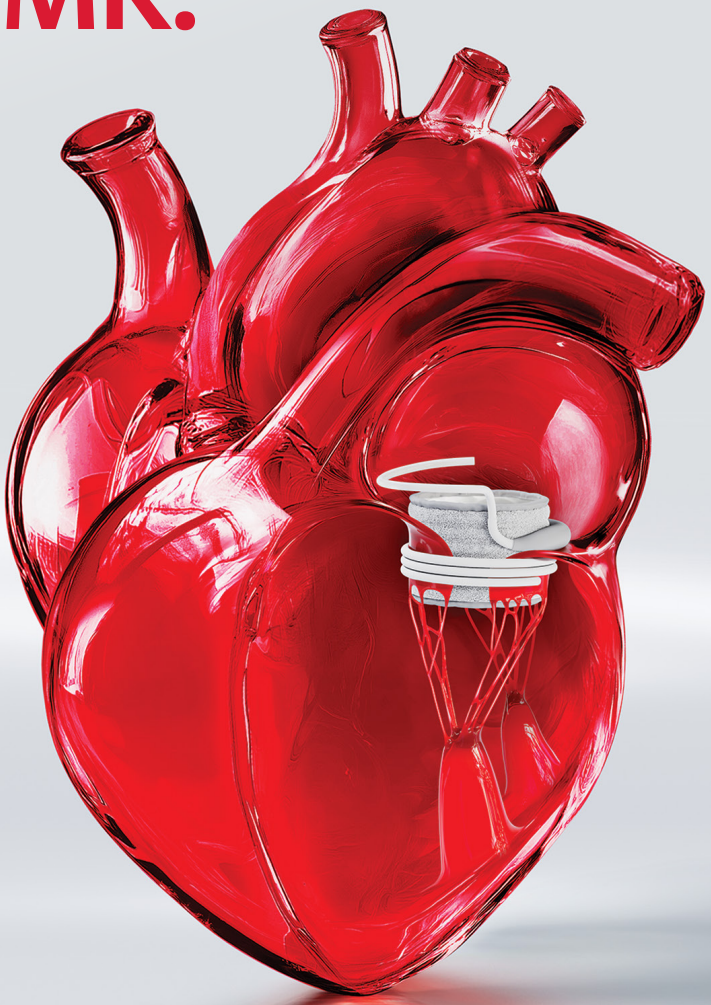
Introducing the SAPIEN M3 System for TMVR

Touch more lives. Treat more MR.

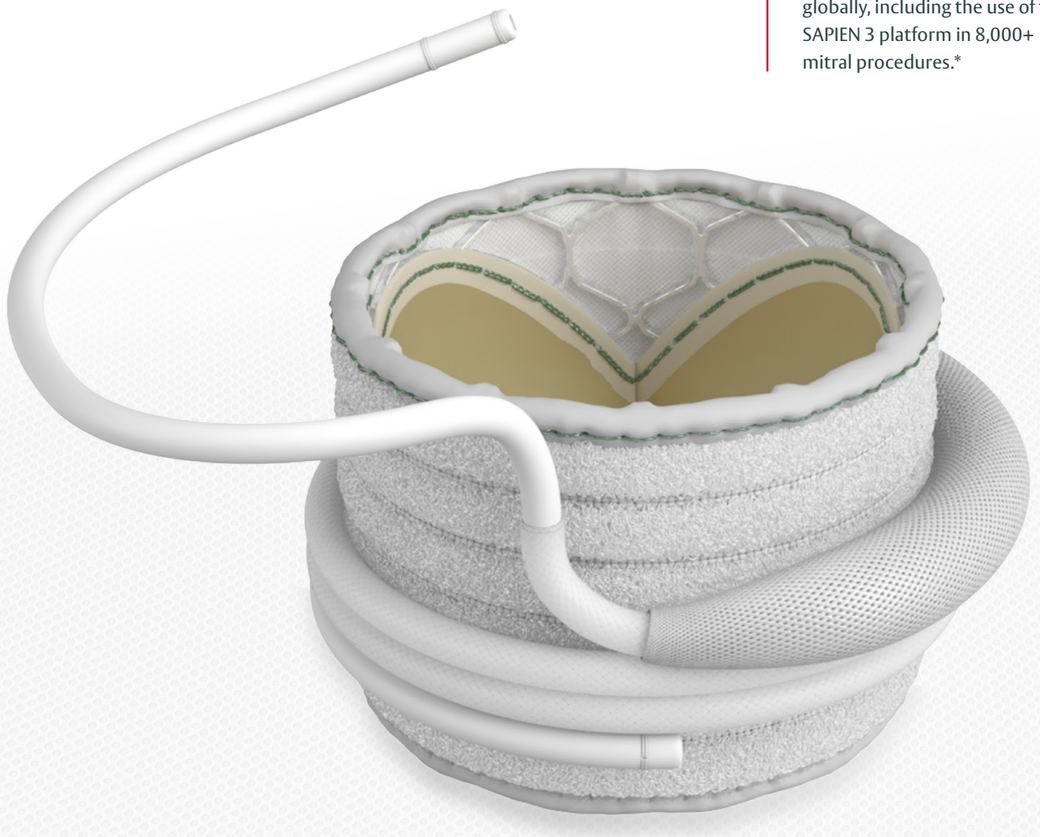


The first and only approved transseptal approach to mitral valve replacement. Built on proven SAPIEN technology, designed to treat mitral regurgitation.

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 8,000+ mitral procedures.*



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

Treat more MR with the SAPIEN M3 system for patients experiencing symptomatic moderate-to-severe or severe MR who are deemed unsuitable for surgery or TEER.

TMVR, transcatheter mitral valve replacement; *MR,* mitral regurgitation; *TEER,* transcatheter edge-to-edge repair.
*As of Q1 2024.

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]	79% 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]	39% of MR patients presented with heart failure[†4]
MR represented an extrapolated annual cost of 350–550M euros[†4]	50% mortality rate for non-operated patients with severe MR at 5 years[8]

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 implant. Two parts. MR treatment reimagined.

The SAPIEN M3 transcatheter mitral valve replacement (TMVR) system substantially reduces mitral regurgitation.†

SAPIEN M3 Dock

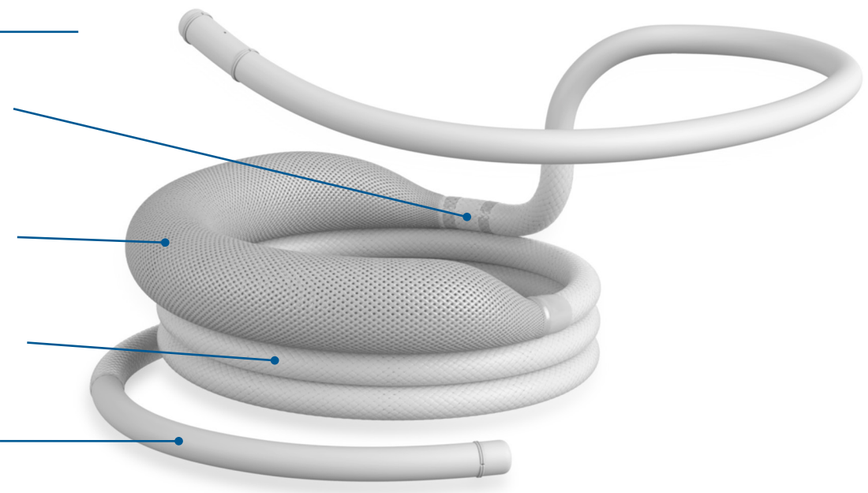
Encircles and captures the native mitral leaflets to create a stable and standardized landing zone for the SAPIEN M3 valve

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

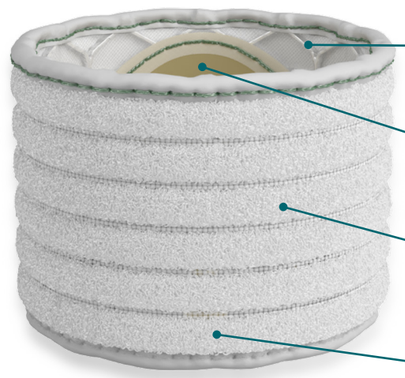
Built on the proven SAPIEN technology, optimized to treat mitral regurgitation

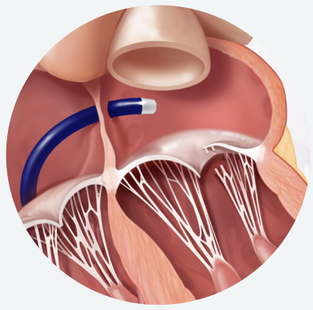
Cobalt-chromium alloy frame
provides radial strength and good visibility under fluoroscopy

Trileaflet bovine pericardial tissue
treated with the ThermaFix tissue process

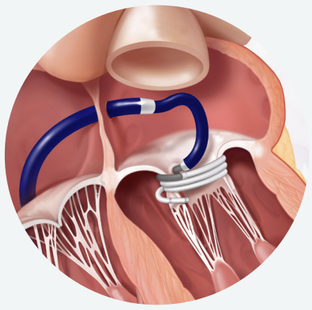
Full-frame PET skirt
respects the native anatomy

Single 29mm valve
can treat a variety of mitral anatomies

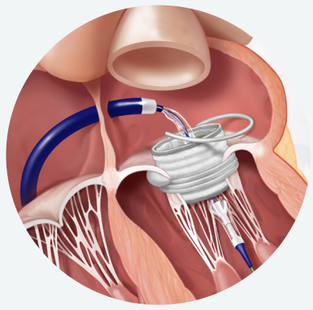




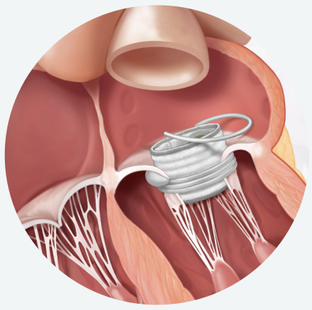
Transseptal access The low-profile Edwards 23F inner diameter guide sheath is used for both the dock and valve delivery, providing a minimally invasive transseptal approach to TMVR.[11]



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.



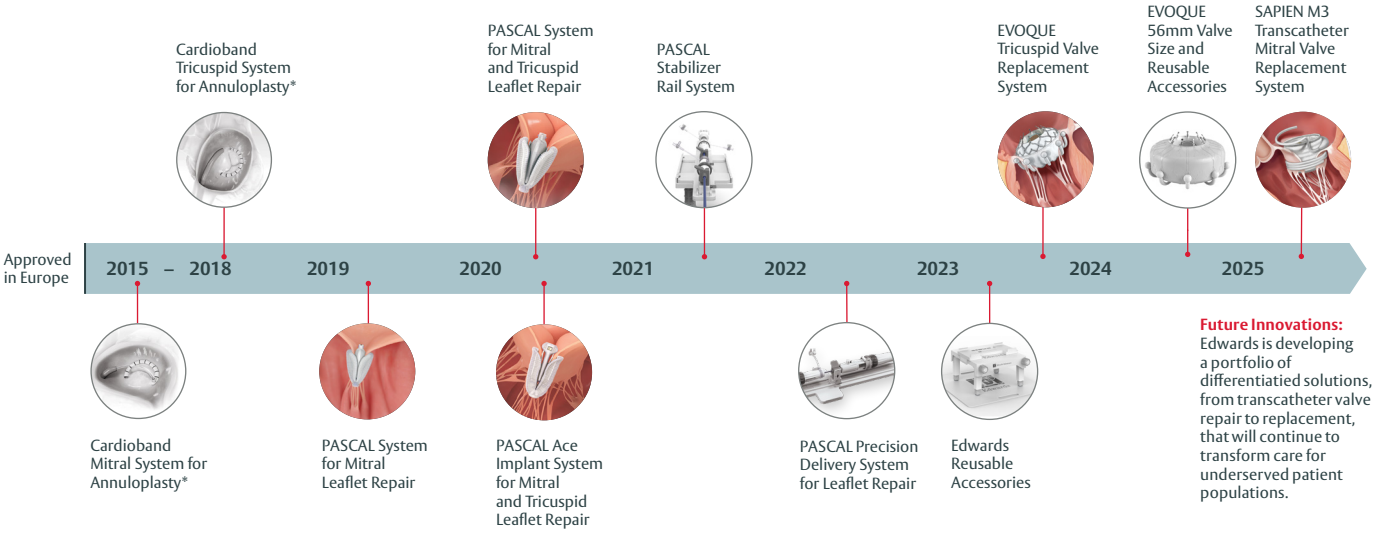
Final implant The SAPIEN M3 system substantially reduces MR and improves quality of life.†

PET, polyethylene terephthalate.
† Summary of Safety and Clinical Performance (SSCP) on file.

11 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.



Future Innovations: Edwards is developing a portfolio of differentiated solutions, from transcatheter valve repair to replacement, that will continue to transform care for underserved patient populations.

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

Learn more about the SAPIEN M3 system at Edwards.com/gb/SAPIENM3.

References

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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 where applicable).

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