

Versatility,
accuracy,
and control,
in your hands

Edwards PASCAL Precision
Transcatheter Valve Repair System



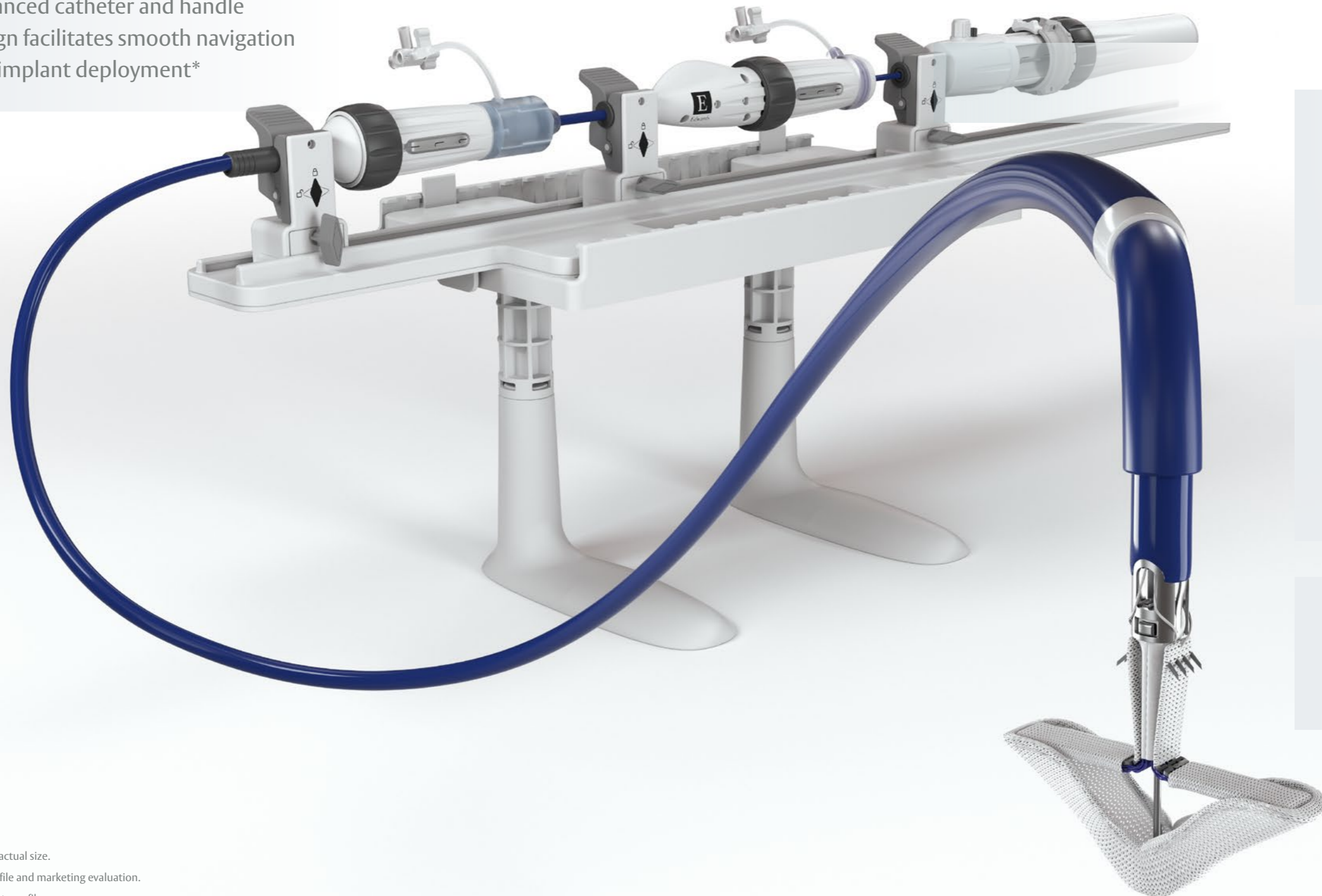
Edwards

Introducing the PASCAL Precision System

Designed for versatility, accuracy, and control

Accurate, Intuitive Control

Advanced catheter and handle design facilitates smooth navigation and implant deployment*



Atraumatic clasp and closure

Enhance leaflet capture with atraumatic reclip capabilities

Versatile implant configuration

Adapt to specific procedural and anatomical needs

Predictable release

Deploy the implant with procedural confidence^{1†}

¹Images are not actual size.

*Design data on file and marketing evaluation.

†Performance data on file.

Designed for precise placement with accurate, intuitive control*

Advanced catheter and handle design facilitates smooth navigation and implant deployment*

Catheter control

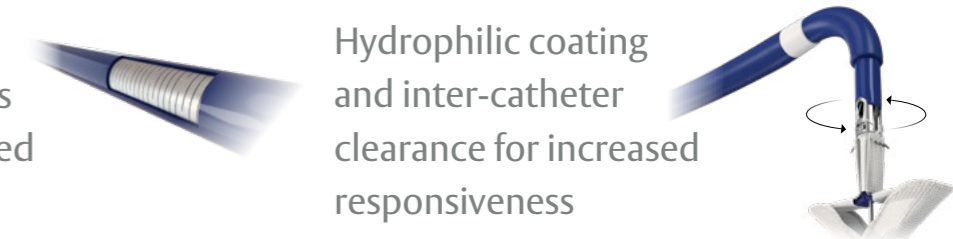
Independent catheters allow for maneuvering within 3 planes

1 Secure stabilizers
Incremental movements and fine adjustments to advance, retract, and maneuver catheters*

2 Responsive catheter design
Optimized torque transfer to facilitate implant placement†

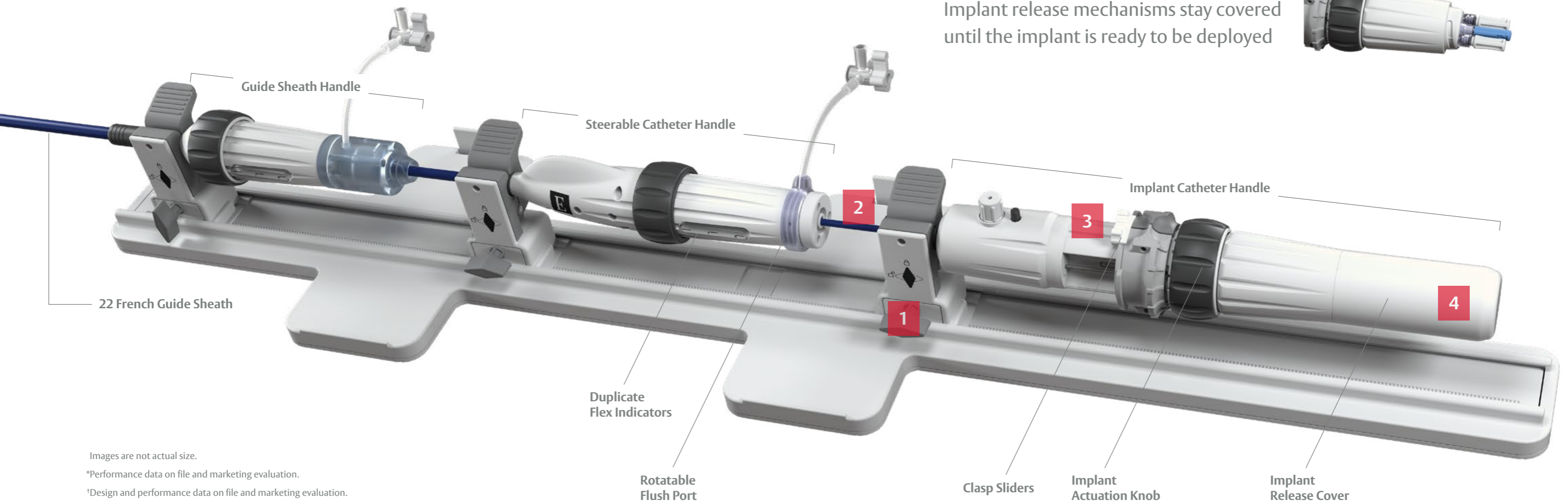
Laser-cut hypotube technology provides stability and balanced catheter flexibility

Hydrophilic coating and inter-catheter clearance for increased responsiveness



3 Ergonomic manipulation
Redesigned clasp sliders allow for both independent and simultaneous clamping, while the implant actuation knob provides full implant configuration control‡

4 Simple release
Implant release mechanisms stay covered until the implant is ready to be deployed



Images are not actual size.

*Performance data on file and marketing evaluation.

†Design and performance data on file and marketing evaluation.

‡Design data on file and marketing evaluation.

Atraumatic clasp and closure help you preserve leaflet integrity*

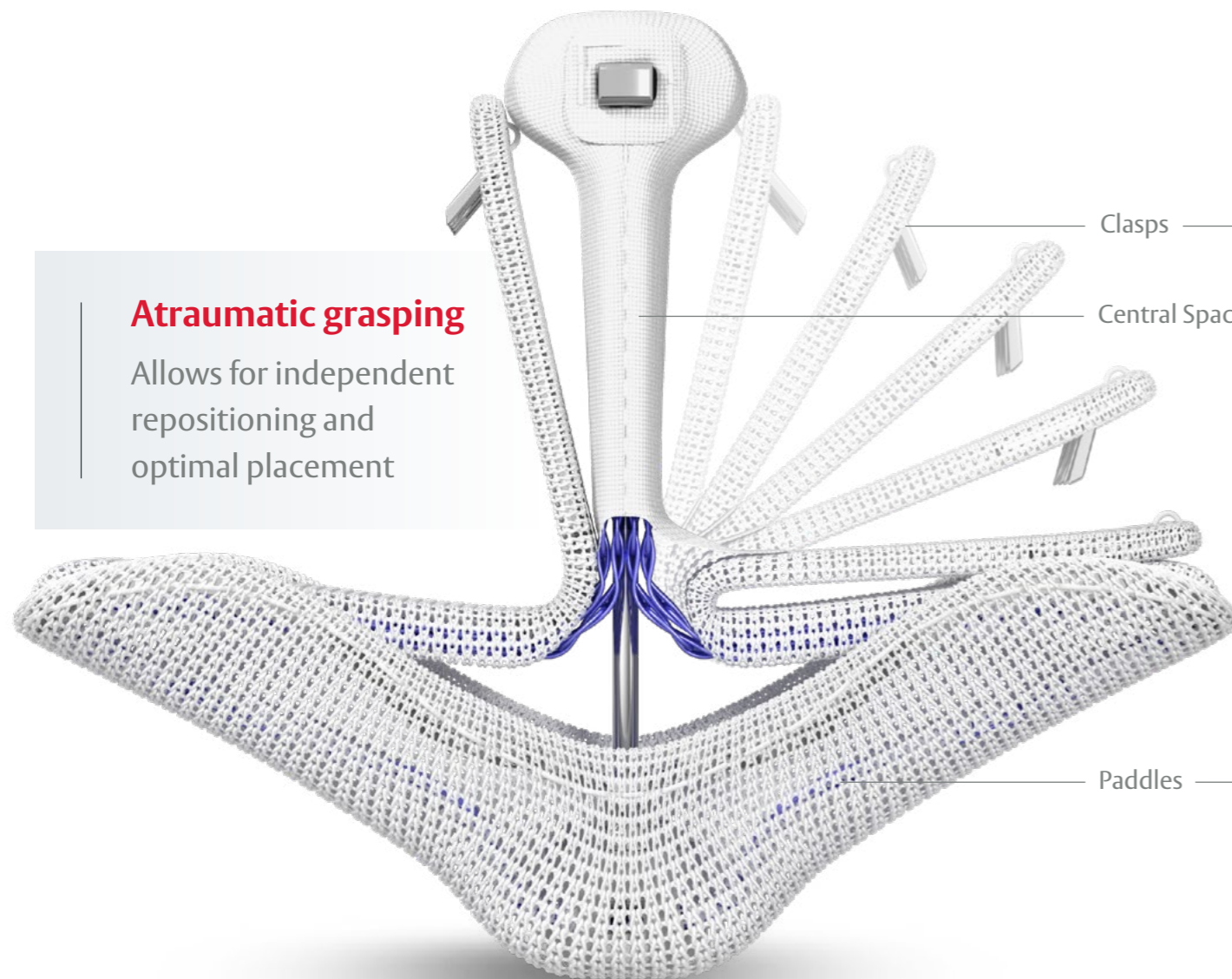
Enhance leaflet capture with atraumatic reclasp capabilities

Close the implant to conform to native anatomy and flex during the cardiac cycle



Nitinol construction

Spring-like closure and dynamic implant flexing



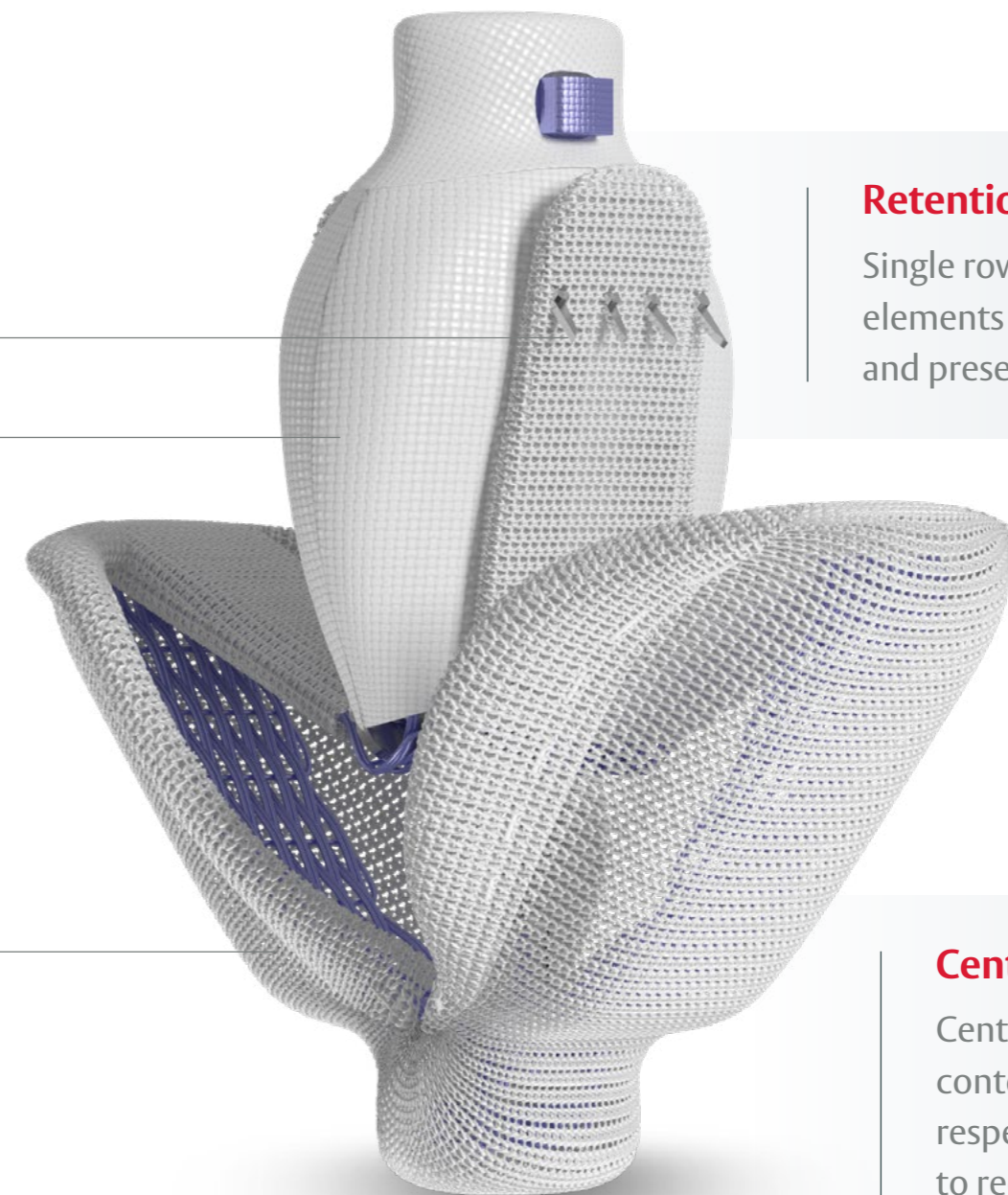
Atraumatic grasping

Allows for independent repositioning and optimal placement

Clasps

Central Spacer

Paddles



Retention elements

Single row of retention elements to clasp, reclasp, and preserve leaflets

Central spacer

Central spacer and contoured paddles respect native anatomy to reduce leaflet stress†

PASCAL Ace Implant

PASCAL Implant

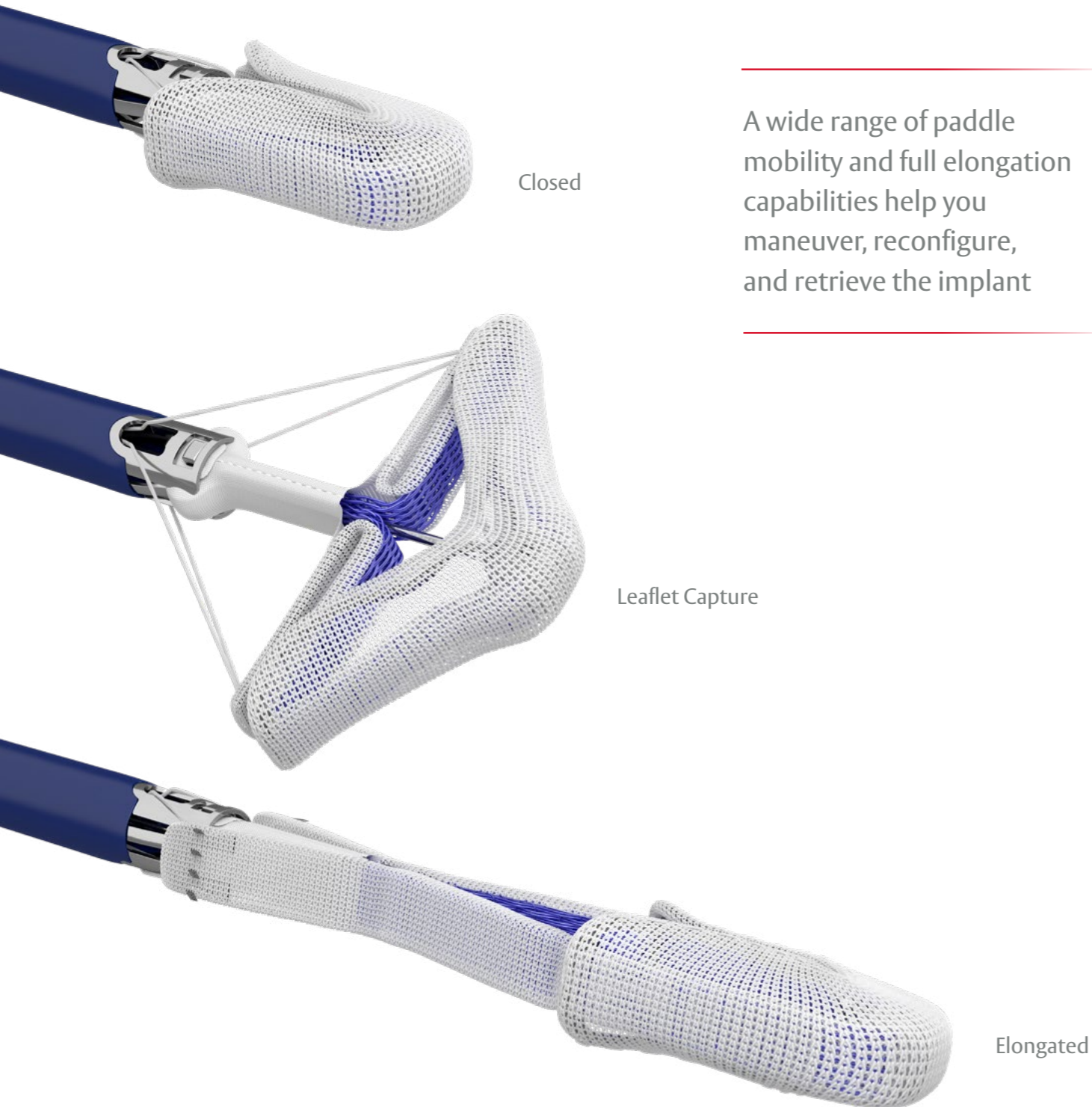
Images are not actual size.

*Performance and simulation data on file.

†Performance data on file.

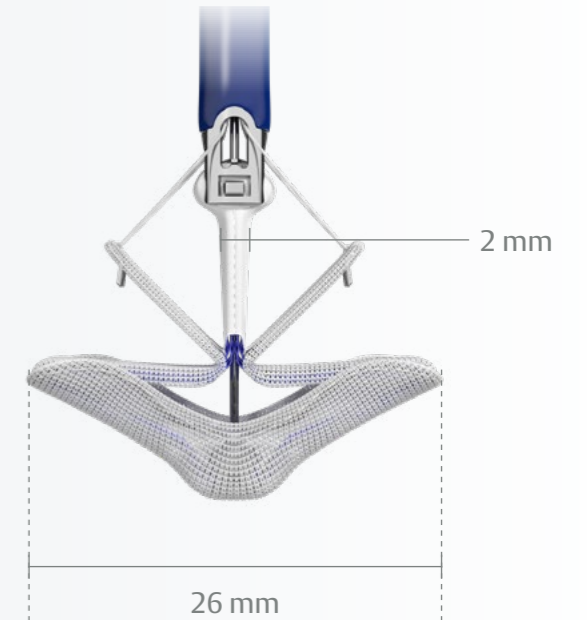
Navigate a range of anatomies with versatile implant configuration^{2*}

Adapt to your specific procedural and anatomical needs

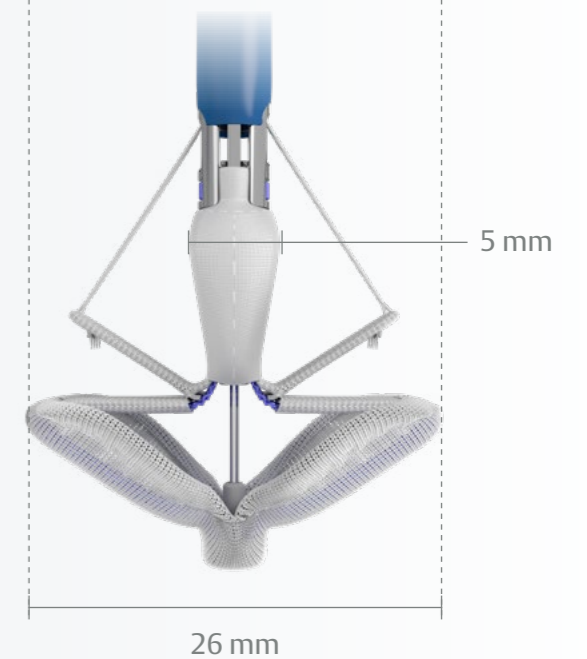


Distinct implant designs, same functionality

PASCAL Ace



PASCAL



Images are not actual size.

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Shown: PASCAL Ace implant; also applicable for PASCAL implant. Images are not actual size.

*Performance data on file.

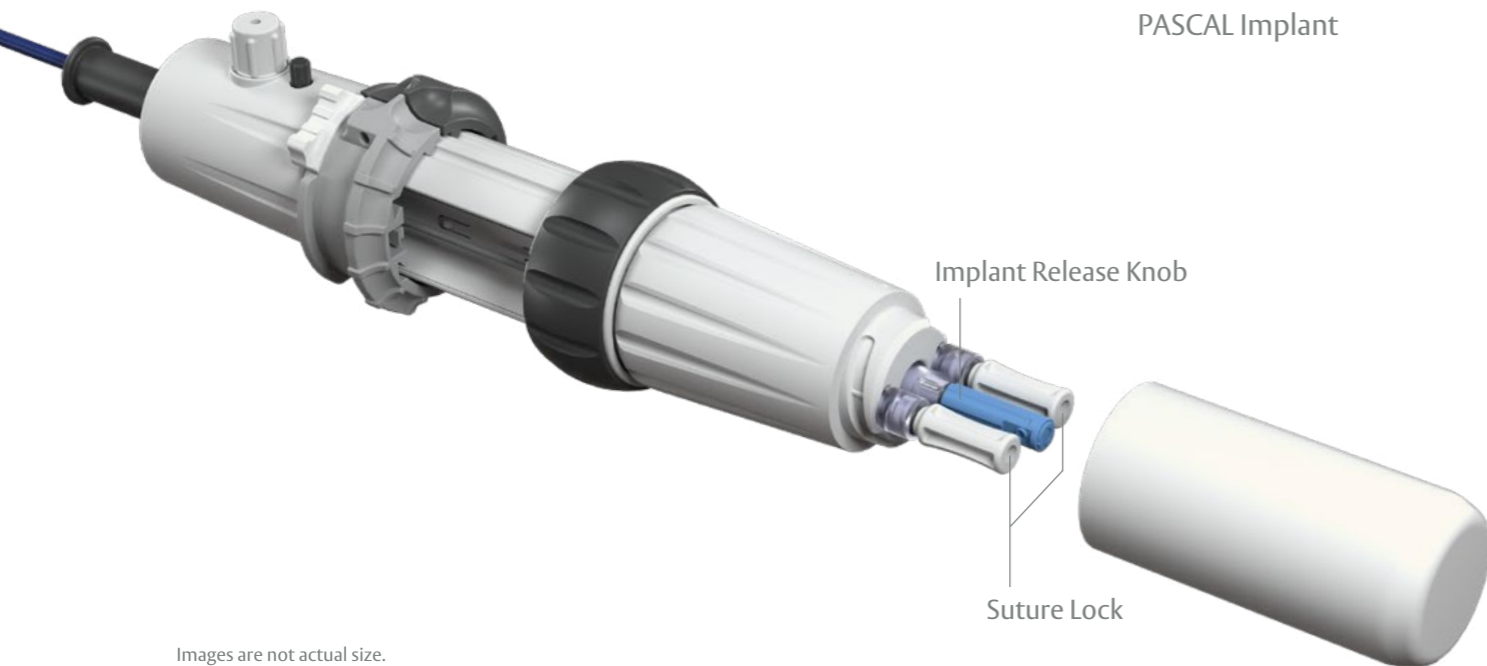
Post-implant release predictability you expect*

Deploy the implant with procedural confidence

With an implant designed to adapt to native anatomies and a catheter with balanced flexibility, what you see before release is what you can achieve*



PASCAL Implant



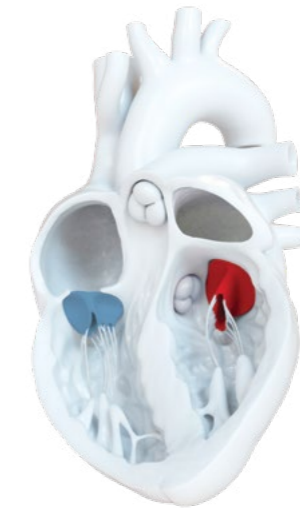
To learn more about the benefits of the PASCAL Precision System, **connect with your local Edwards sales representative.**

Edwards Lifesciences is committed to continuing a robust clinical trial program⁴

THE CLASP TR STUDY

THE CLASP II TR TRIAL

THE TriCLASP STUDY



THE CLASP STUDY

THE CLASP IID/IIF TRIAL

THE MiCLASP STUDY



Clinical study data is also available to review online at [Edwards.com/PASCAL](https://www.edwards.com/PASCAL)

Images are not actual size.

*Performance data on file.

Leading the way in MR and TR innovation

Edwards is committed to advancing the treatment of mitral regurgitation (MR) and tricuspid regurgitation (TR) for the patients who can be treated and to significantly improve their quality of life^{1,3}

2019



PASCAL Implant System for MR

Introduction of PASCAL Repair System uniquely designed to enhance leaflet capture and close the coaptation gap¹

2020



PASCAL Implant System for TR

PASCAL Implant System for TR expanded indication for even challenging tricuspid anatomies^{2*}



PASCAL Ace Implant System for MR and TR

A narrower profile designed for ease-of-navigation in complex anatomies

2021



PASCAL Stabilizer Rail System

Enhanced stability to advance, retract, and torque catheters

2022



PASCAL Precision System

Delivery system catheters, handles, and stabilizers optimally designed for versatility, accuracy, and control



Watch the PASCAL Precision System in action at
[Edwards.com/PASCAL](https://www.edwards.com/PASCAL)

*Instructions For Use.

References:

1. Szerlip M, Spargias KS, Makkar R, et al. 2-Year outcomes for transcatheter repair in patients with mitral regurgitation from the CLASP study. *JACC Cardiovasc Interv.* 2021;14(14):1538-1548. 2. Fam NP, Braun D, von Bardeleben RS, et al. Compassionate use of the PASCAL transcatheter valve repair system for severe tricuspid regurgitation: a multicenter, observational, first-in-human experience. *JACC Cardiovasc Interv.* 2019;12(24):2488-2495. 3. Hahn R. Transcatheter tricuspid valve repair: CLASP TR study one-year results. Presented at LBT EuroPCR2022 <https://course.pconline.com/en/vod/late-breaking-mitral-and-tricuspid-studies-and-registries>. 4. Clinicaltrials.gov NCT03745313, NCT04097145, NCT04614402, NCT03170349, NCT03706833, NCT04430075.

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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