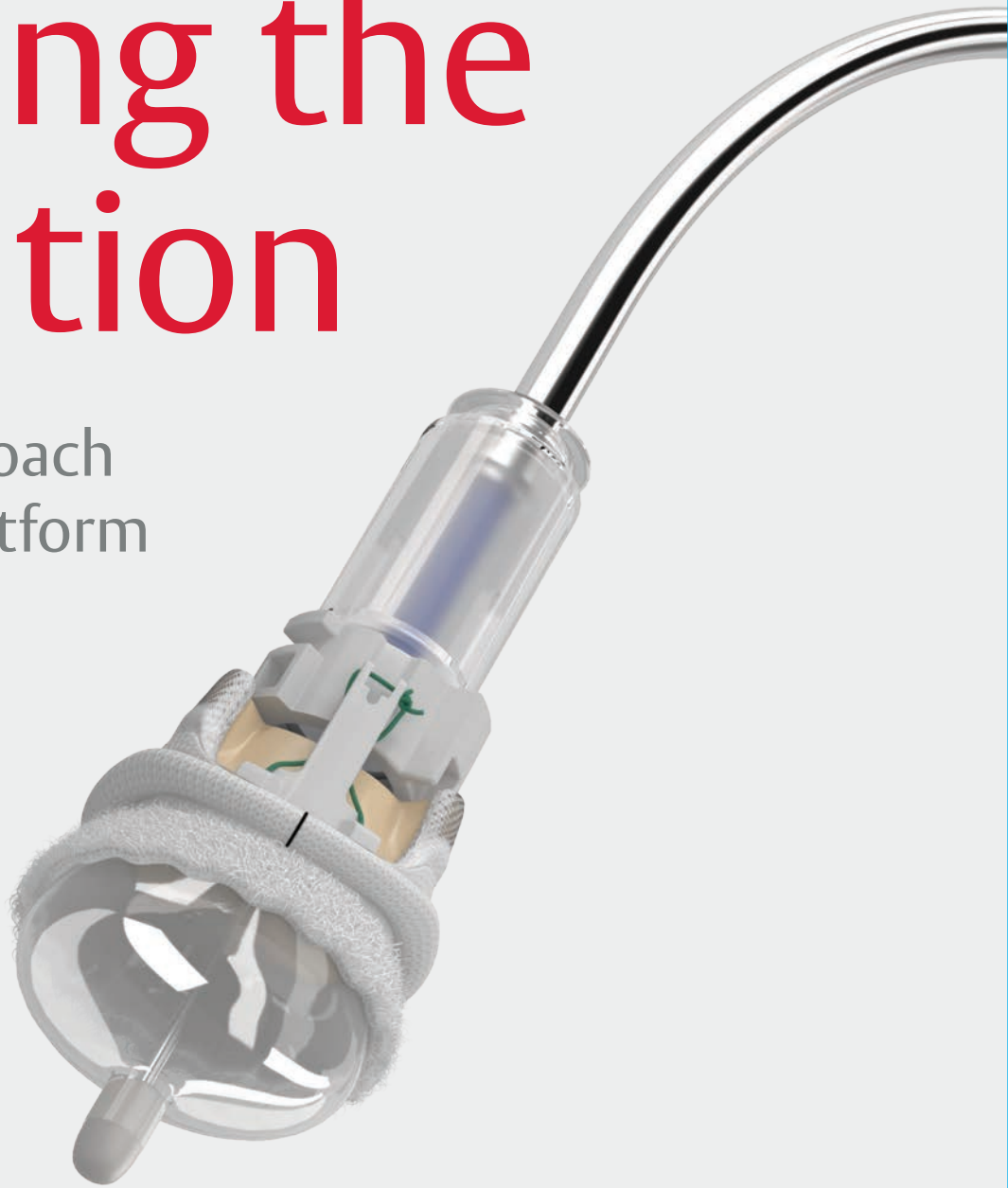


Leading the Evolution

Advanced approach
on a proven platform



EDWARDS INTUITY Elite
Valve System



Edwards

The EDWARDS INTUITY Elite valve system represents our commitment to continued innovation for surgeons and patients in heart valve therapy.

Our commitment to surgical innovation

The surgical heart valve market is evolving. **Concomitant procedures** are becoming a larger percent of the surgical mix, and **MIS** is gaining in importance. To enable surgeons to address these trends, we have developed the EDWARDS INTUITY Elite valve system.

We have combined our **proven pericardial valve technology** with our **innovations in transcatheter heart valves** to create a category of surgical valves designed to streamline procedures and well combined with small incisions. We believe more efficient, less invasive procedures can provide significant benefits, both during the procedure and after.

This is the next evolution of surgical aortic valves.

This is the EDWARDS INTUITY valve platform.

Evolution of a trusted design

The **EDWARDS INTUITY Elite valve system** is designed to achieve three important goals simultaneously:

Built on a
trusted, proven
valve platform



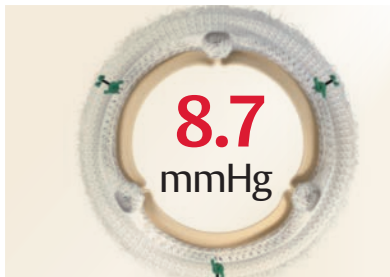
Well combined with
small incisions

Streamlines
concomitant
procedures

Built on a trusted, proven valve platform

Designed for durability. Created to last.

The EDWARDS INTUITY Elite valve system combines our proven pericardial valve technology with our innovations in transcatheter heart valves.



Excellent 3-year hemodynamics[†]

Single-digit mean gradients (8.7 mmHg overall n = 59) demonstrated in the prospective, multi-center TRITON trial of 287 patients!



Low supra-annular profile for maximum options

Low supra-annular profile facilitates use with any aortotomy and provides excellent clearance from the coronary ostia.

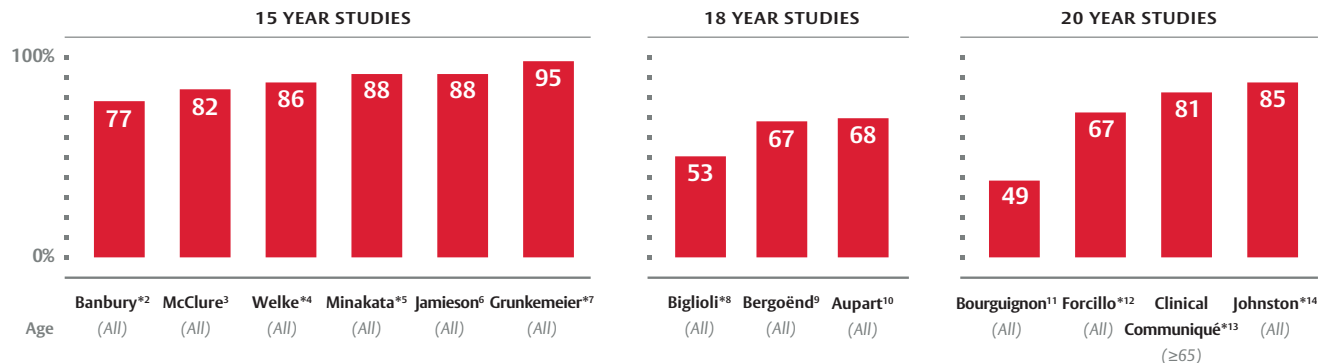


Built on the PERIMOUNT valve performance

The EDWARDS INTUITY Elite valve system is built upon the proven performance and long-term durability of the PERIMOUNT valve design. By mounting matched leaflets under the flexible stent, commissural stress points are minimized.

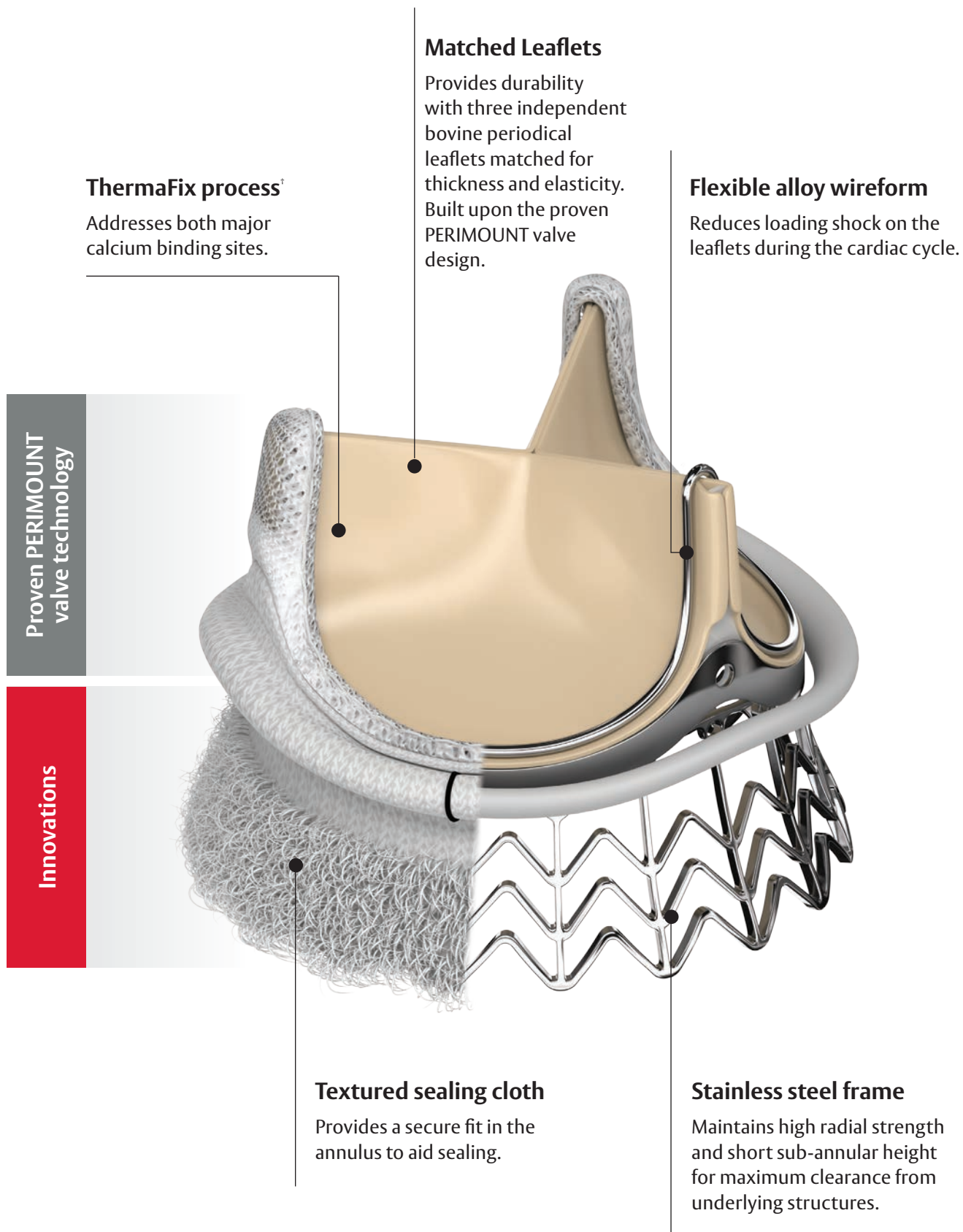
Actuarial freedom from structural valve deterioration

Long-term studies (PERIMOUNT valve)



* Freedom from explant / prosthesis replacement / reoperation due to SVD

2 † These data pertain to an earlier generation EDWARDS INTUITY valve as part of the TRITON trial.



ThermaFix process†

Addresses both major calcium binding sites.

Matched Leaflets

Provides durability with three independent bovine periodical leaflets matched for thickness and elasticity. Built upon the proven PERIMOUNT valve design.

Flexible alloy wireform

Reduces loading shock on the leaflets during the cardiac cycle.

Proven PERIMOUNT valve technology

Innovations

Textured sealing cloth

Provides a secure fit in the annulus to aid sealing.

Stainless steel frame

Maintains high radial strength and short sub-annular height for maximum clearance from underlying structures.

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

Provides rapid deployment for streamlined procedures

Streamlined implantation. Because time is precious.

Implantation of the EDWARDS INTUITY Elite valve system is streamlined to help reduce procedural steps.

Secure assembly

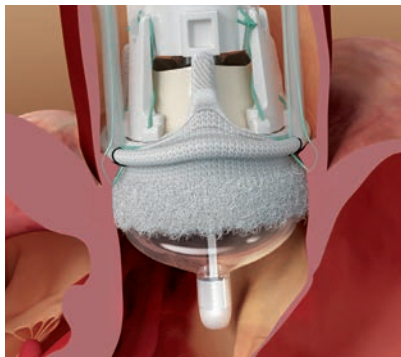
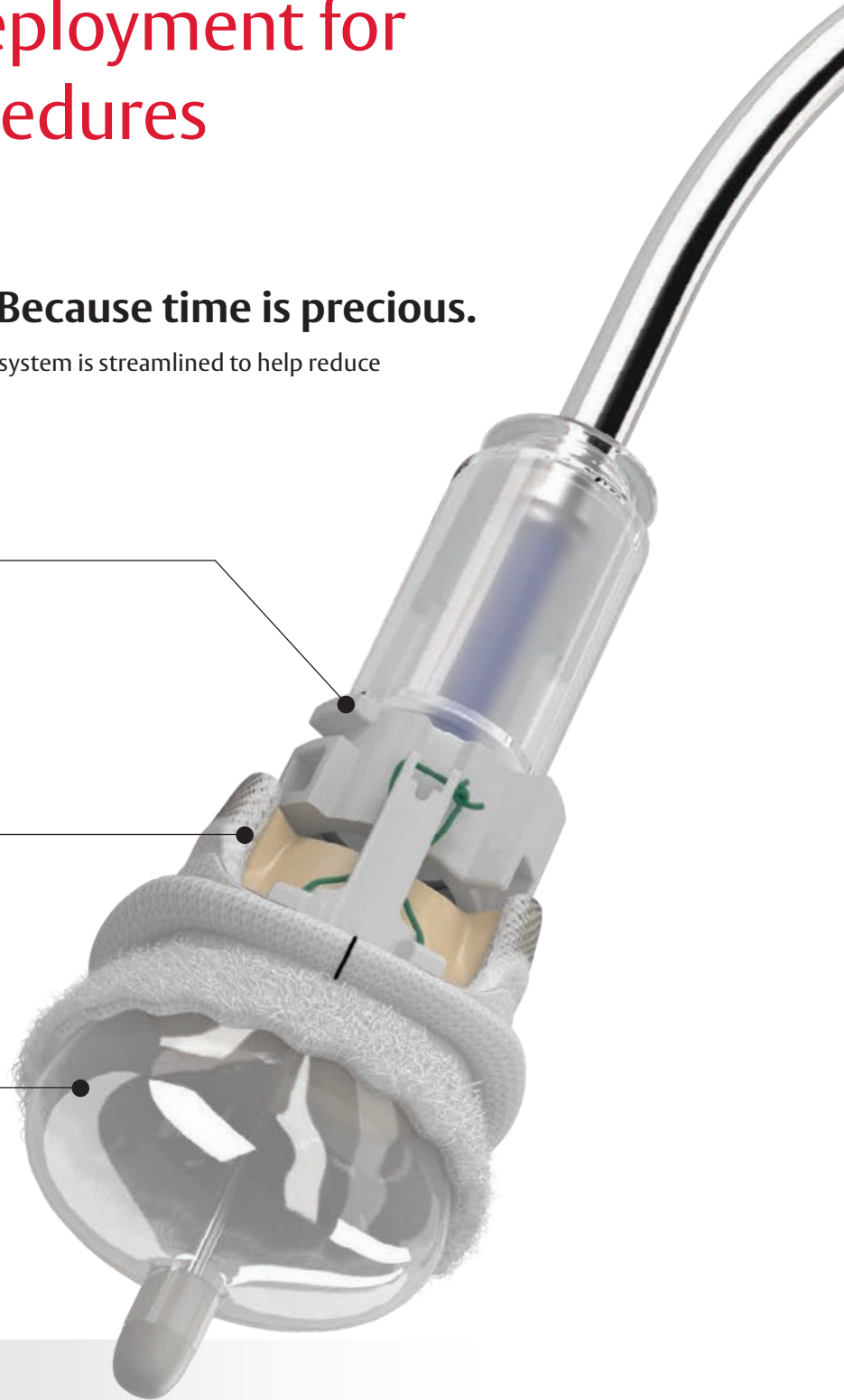
Engineered to ensure only the correct size valve and delivery system are connected for procedural confidence.

Rapid valve preparation

No collapsing or folding of the valve leaflets during preparation or implantation.

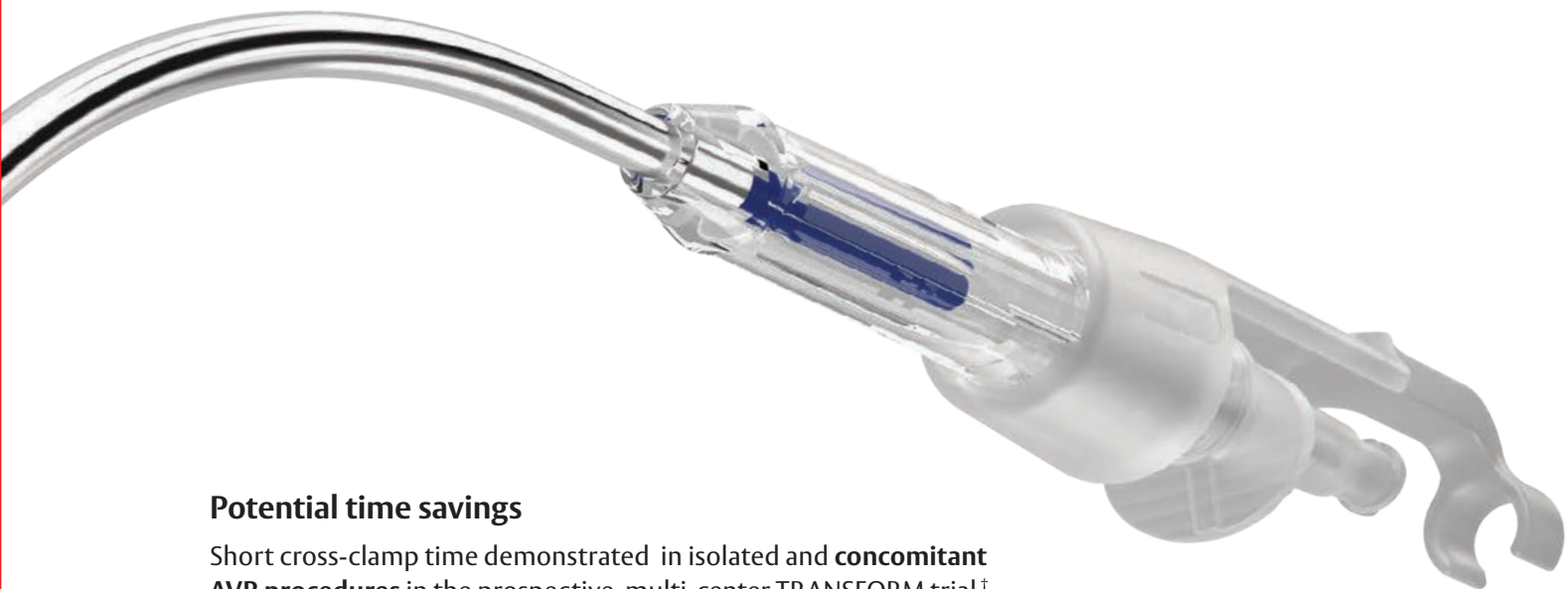
Innovative balloon design

Incorporated within the delivery system for reliable balloon positioning and inflation, as well as simplified device preparation.



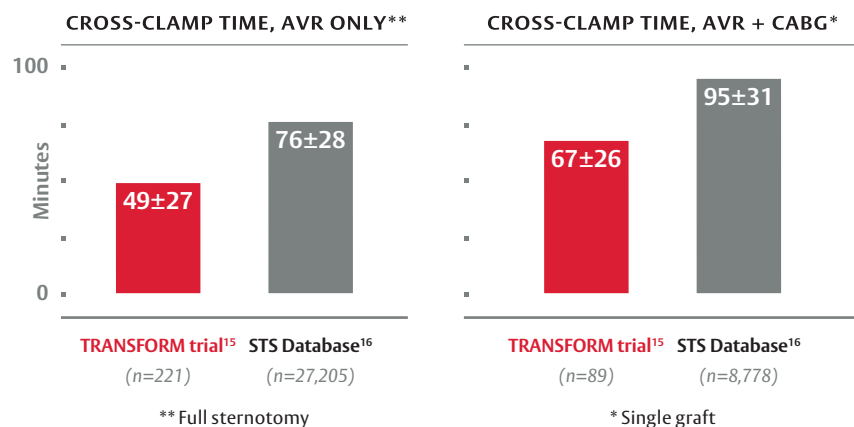
Balloon expanded delivery for efficient procedures

The EDWARDS INTUITY Elite valve system utilizes three guiding sutures in conjunction with the expanded frame for secure annular placement, helping reduce procedural steps.

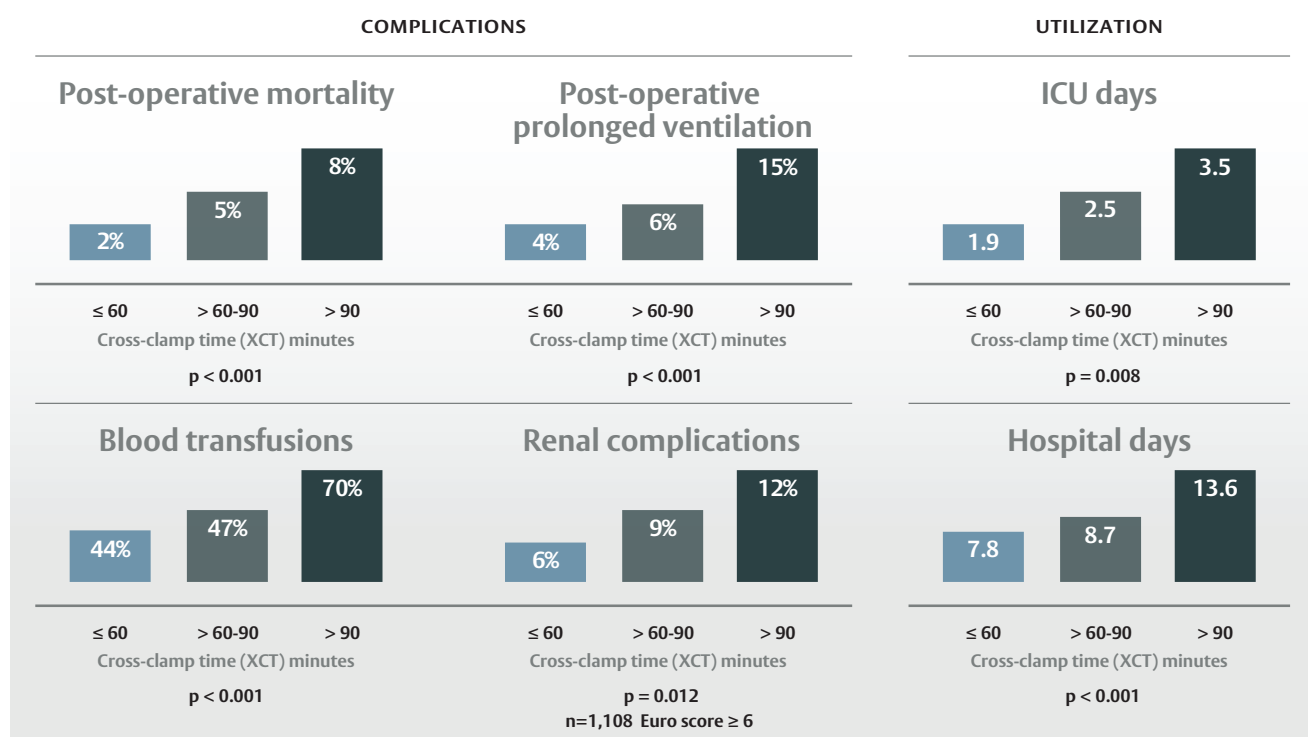


Potential time savings

Short cross-clamp time demonstrated in isolated and **concomitant AVR procedures** in the prospective, multi-center TRANSFORM trial.[†]



Shorter cross-clamp times generally lead to reduced complications and hospital utilization rates^{17†}



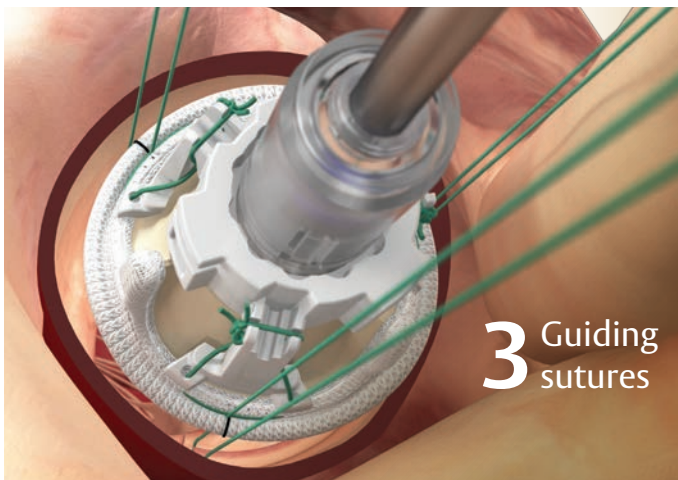
[†] Refer to Table 13 in the product's Instructions for Use

[†] In both low- and high-risk cardiac surgery

Facilitates small incision surgery

Empowering multiple approaches. Progress through access.

The EDWARDS INTUITY Elite valve system is designed to enhance the ease of implantation through small incisions by using 3 guiding sutures.

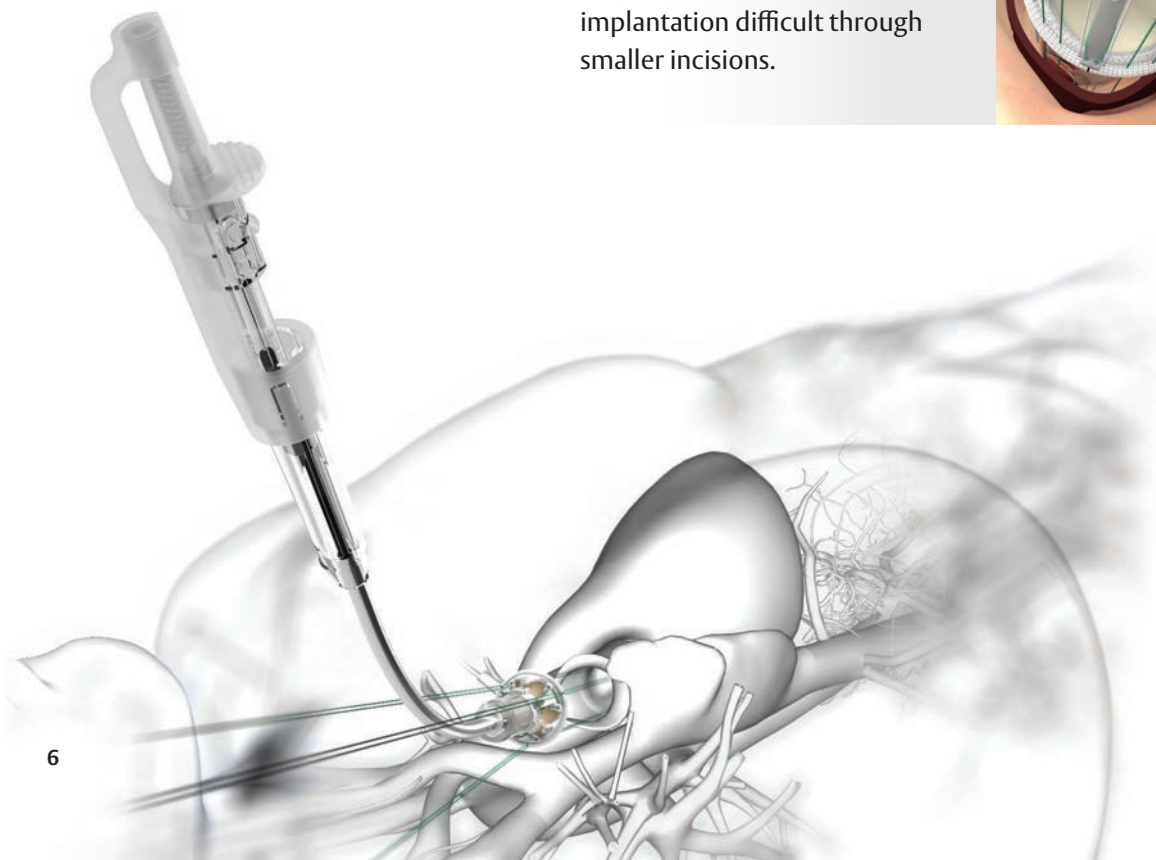
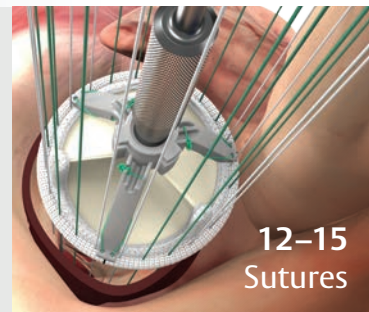


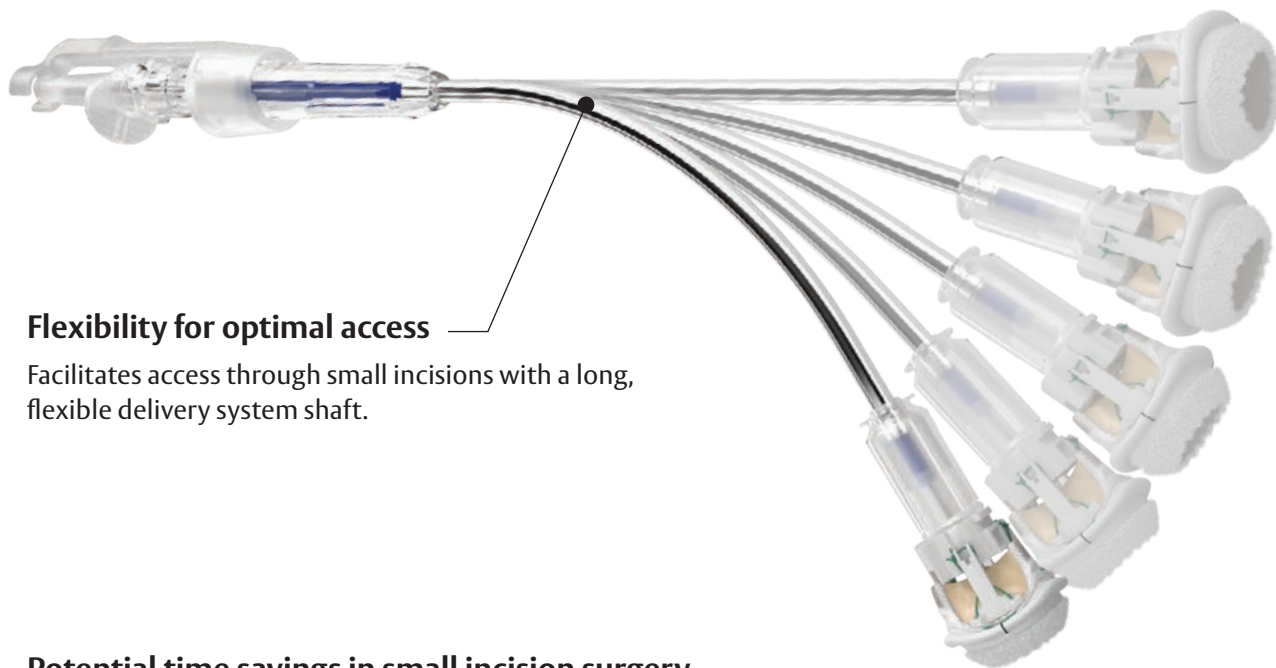
Streamlined delivery

Utilizes a balloon expanded frame and **3 guiding sutures** to provide ease of implantation and excellent visualization.

Traditional surgical valves

Require **12–15 sutures**, making implantation difficult through smaller incisions.

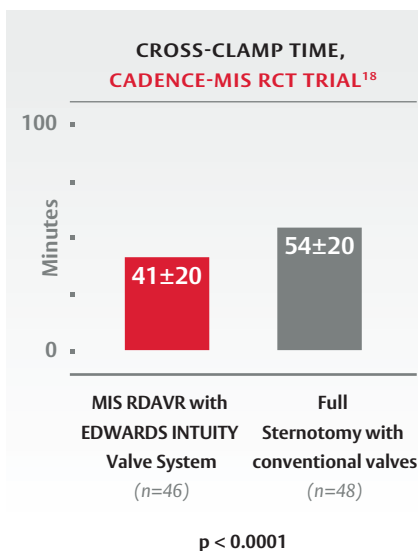
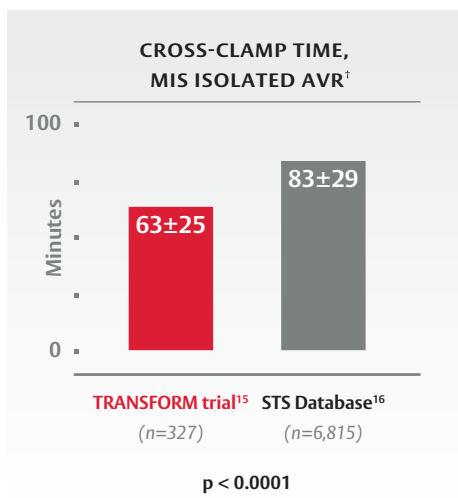




Flexibility for optimal access

Facilitates access through small incisions with a long, flexible delivery system shaft.

Potential time savings in small incision surgery

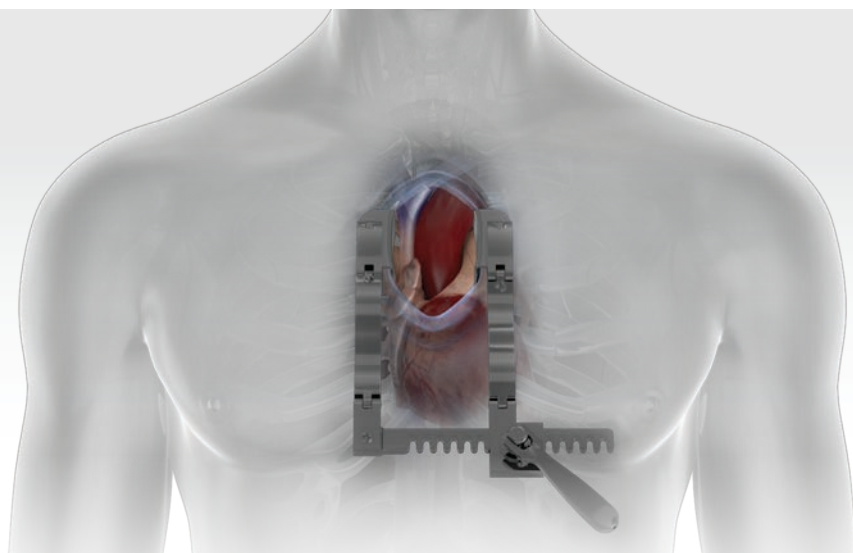


MIS with the EDWARDS INTUITY valve system showed **24% shorter cross clamp time** versus full sternotomy with conventional valves.¹⁸

High use of small incision approaches

The TRITON trial¹ and the TRANSFORM trial¹⁵ showed high rates of small incisions usages in isolated AVR.

58%
(n=414/706)



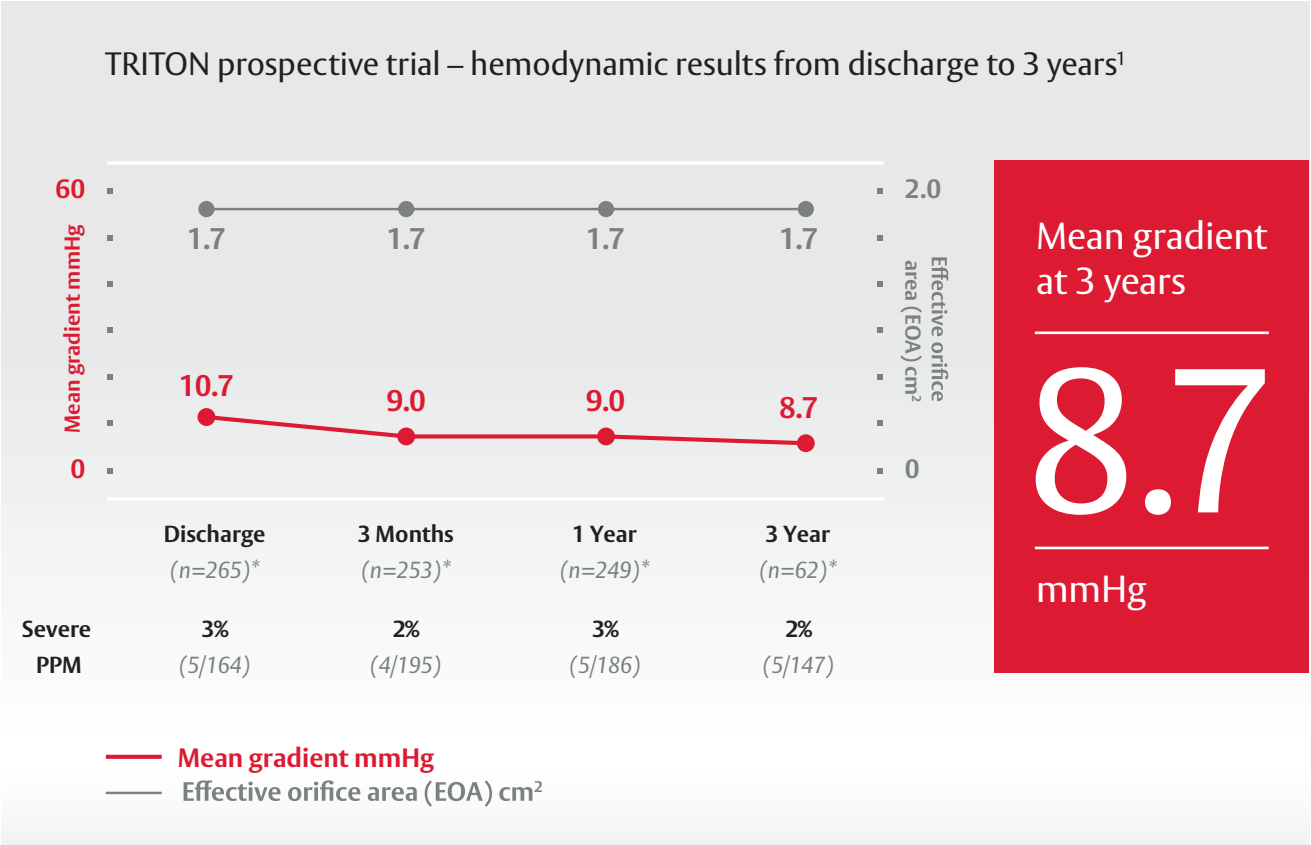
† Refer to Table 13 in the product's Instructions for Use

Excellent hemodynamic performance

The EDWARDS INTUITY valve platform has consistently delivered **low mean pressure gradients** at 1 year, as shown in multiple clinical studies.



In a large prospective trial¹, the EDWARDS INTUITY Elite valve demonstrated **excellent and stable hemodynamic performance** and significant LV mass regression out to 3 years.



* These numbers represent the patients who had a follow up visit during discharge, 3 months, 1 year and 3 years. Not the number of patients for which the EOA and the mean gradient was measured. These data pertain to an earlier generation EDWARDS INTUITY valve as part of the TRITON trial.

A global commitment to clinical evidence

The EDWARDS INTUITY valve system platform is being studied through a robust series of trials and in commercial sites with clinicians across the globe.



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