

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.

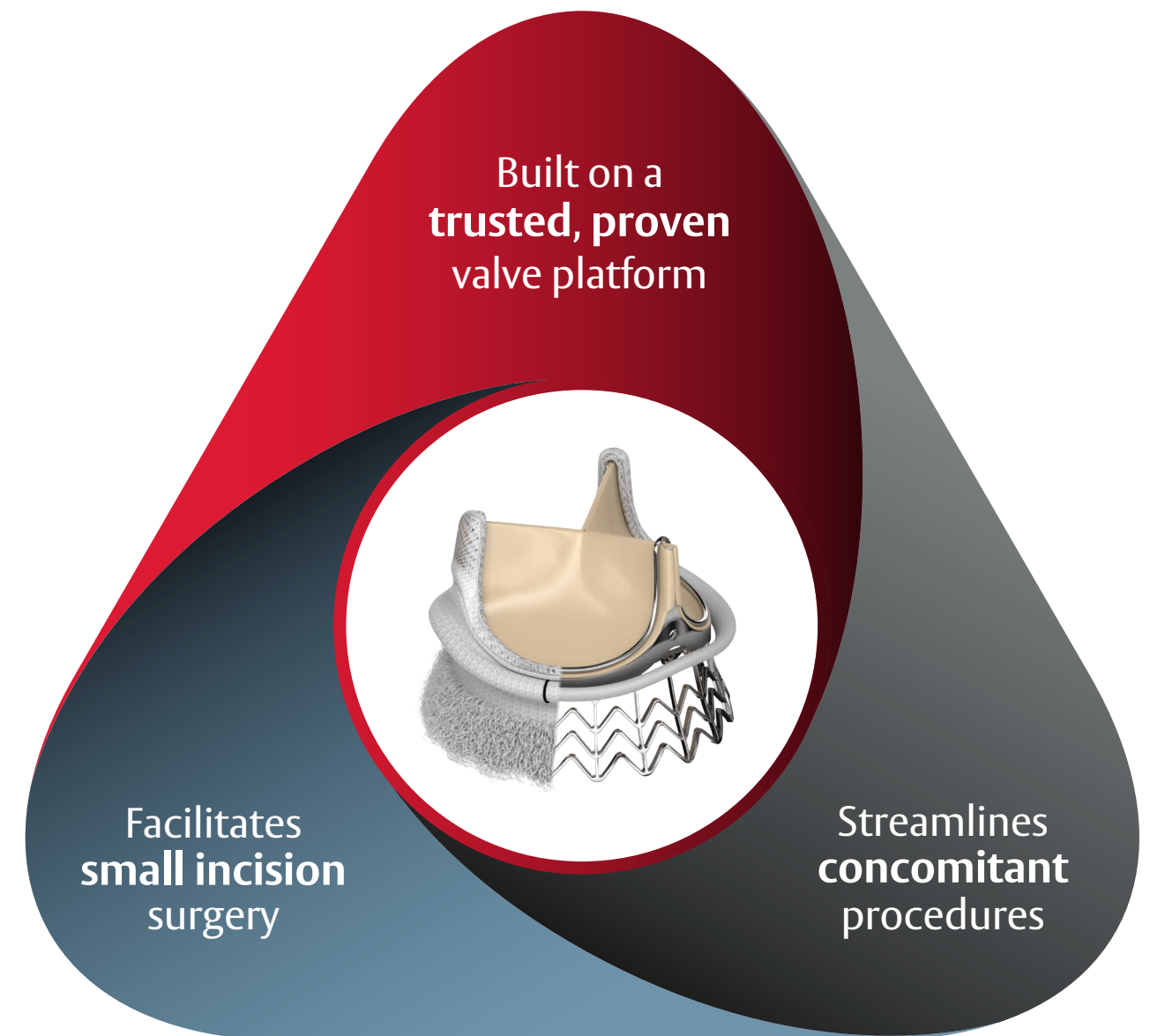
We have combined our **proven pericardial valve technology** with our **innovations in transcatheter heart valves** to create a new category of surgical valves designed to streamline procedures and facilitate smaller incision surgery. We believe more efficient, less invasive procedures can provide significant 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

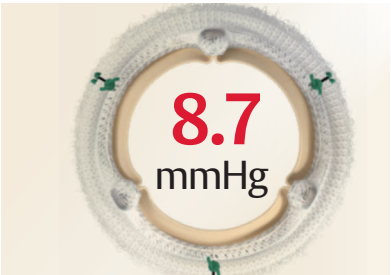
The EDWARDS INTUITY Elite valve system is designed to achieve three important goals simultaneously:



Built on a trusted, proven valve platform

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 patients¹.



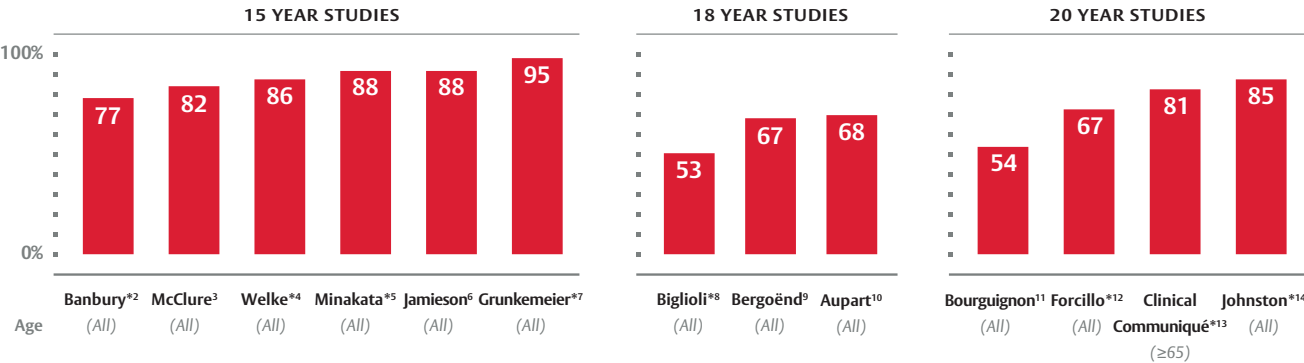
Low supra-annular profile for maximum options
Low supra-annular profile facilitates use with any aortotomy and provides **excellent clearance** from the coronary ostia.



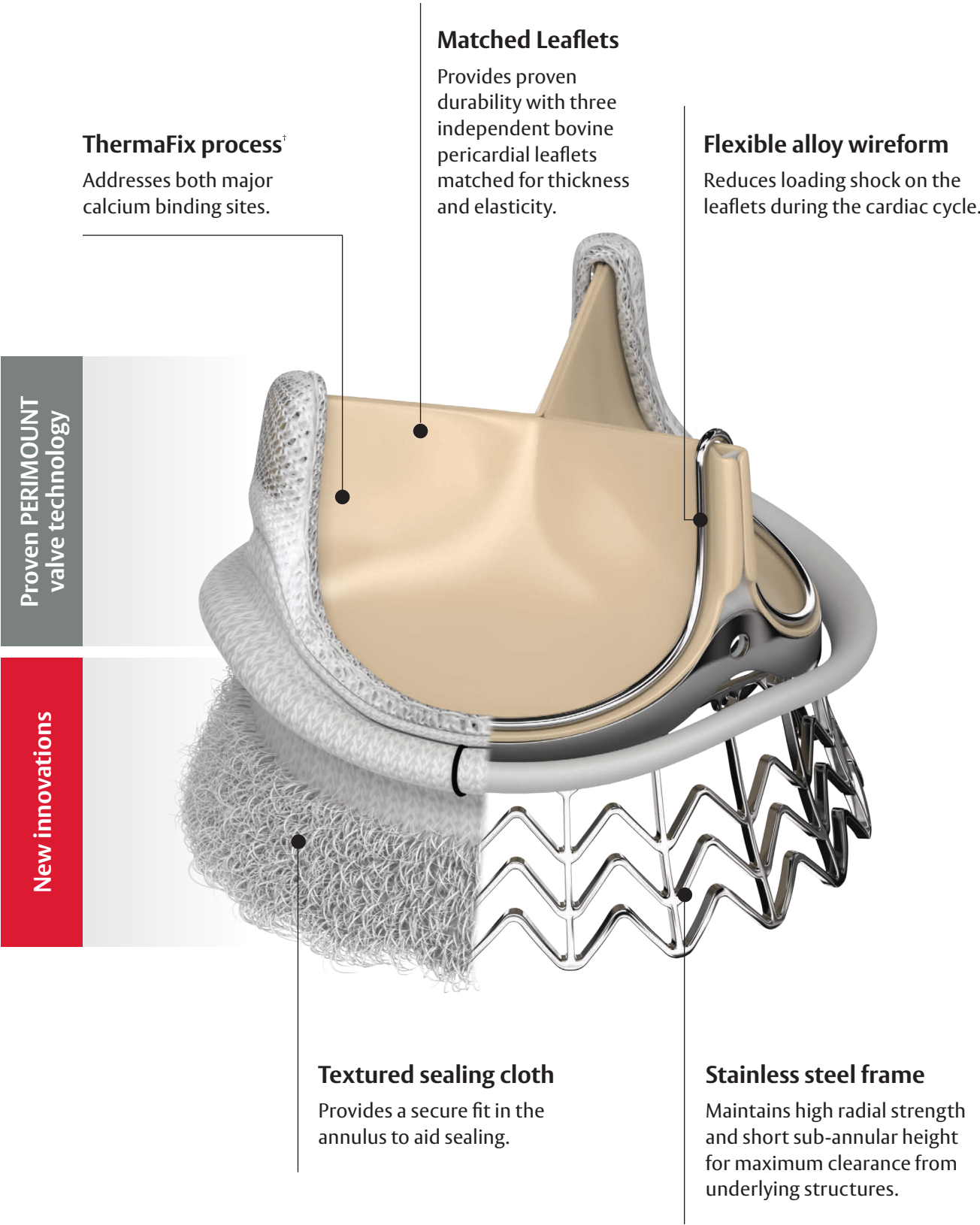
Built on the PERIMOUNT valve performance
The EDWARDS INTUITY Elite valve system is built upon the **proven performance** and **long-term durability** of the PERIMOUNT valve design. By mounting matched leaflets under the flexible stent, commissural stress points are minimized.

Actuarial freedom from structural valve deterioration

Long-term studies (PERIMOUNT valve)



* Freedom from explant / prosthesis replacement / reoperation due to SVD
† These data pertain to an earlier generation EDWARDS INTUITY valve as part of the TRITON trial.



† 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

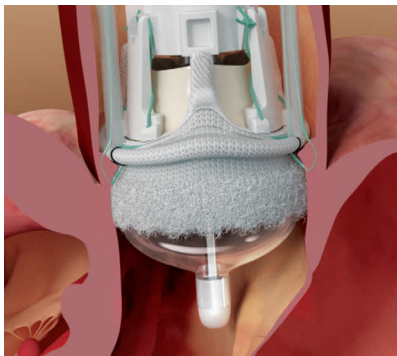
Engineered to ensure only the correct size valve and delivery system are connected for procedural confidence.

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.

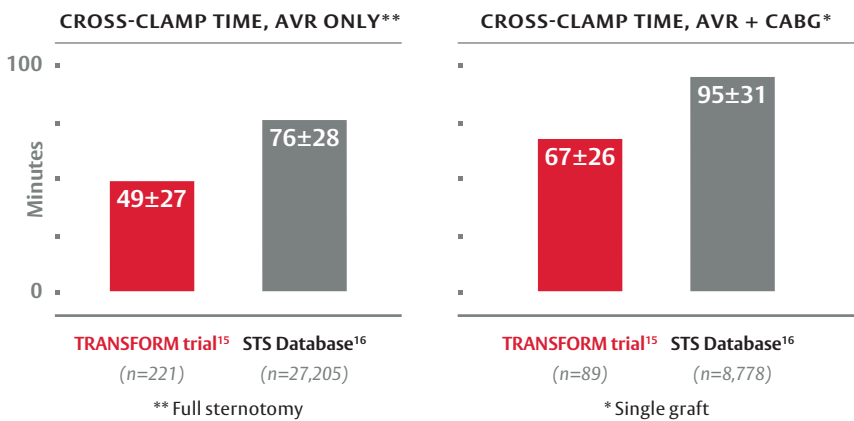


Balloon expanded delivery for efficient procedures

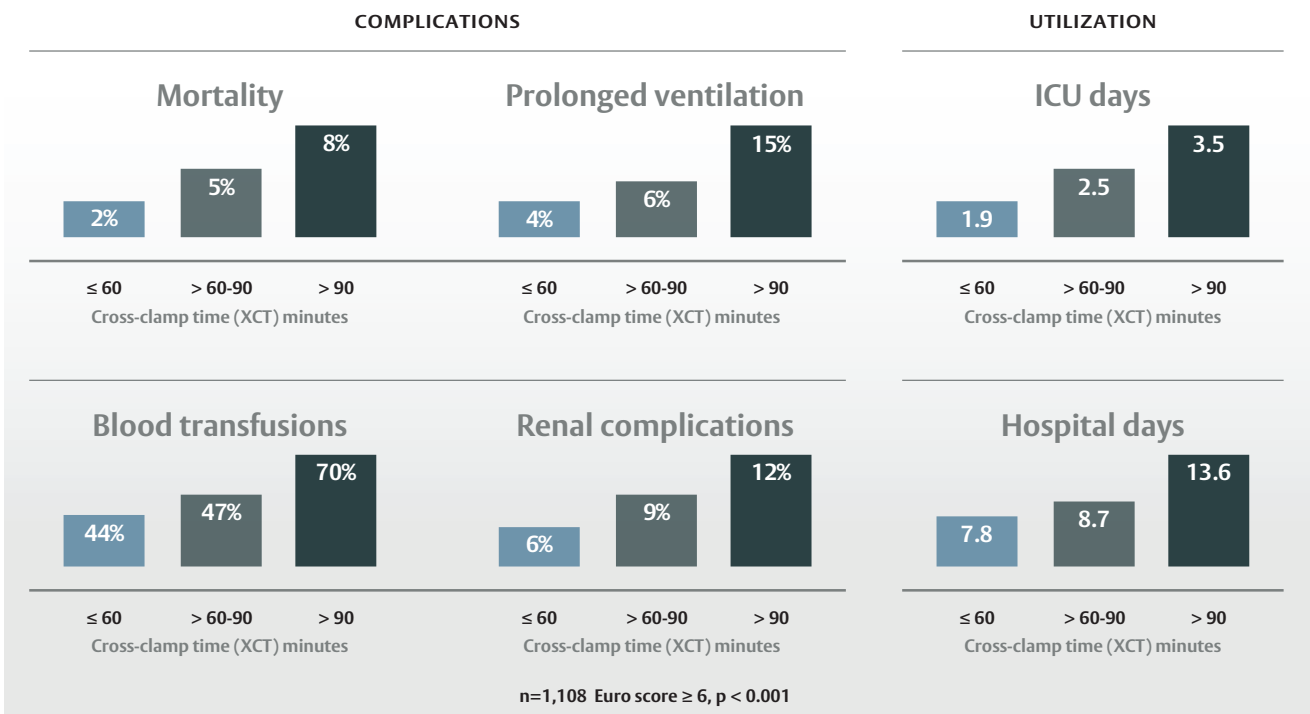
The EDWARDS INTUITY Elite valve system utilizes three guiding sutures in conjunction with the expanded frame for secure annular placement, helping reduce procedural steps.

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†}



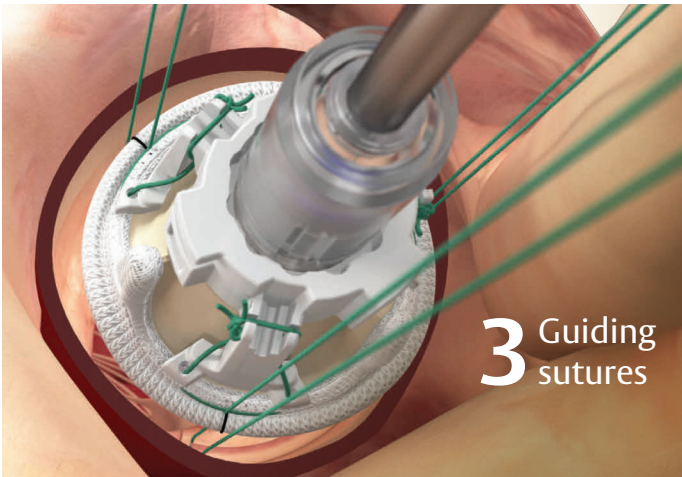
[†] Refer to Table 13 in the product's Instructions for Use

[†] 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

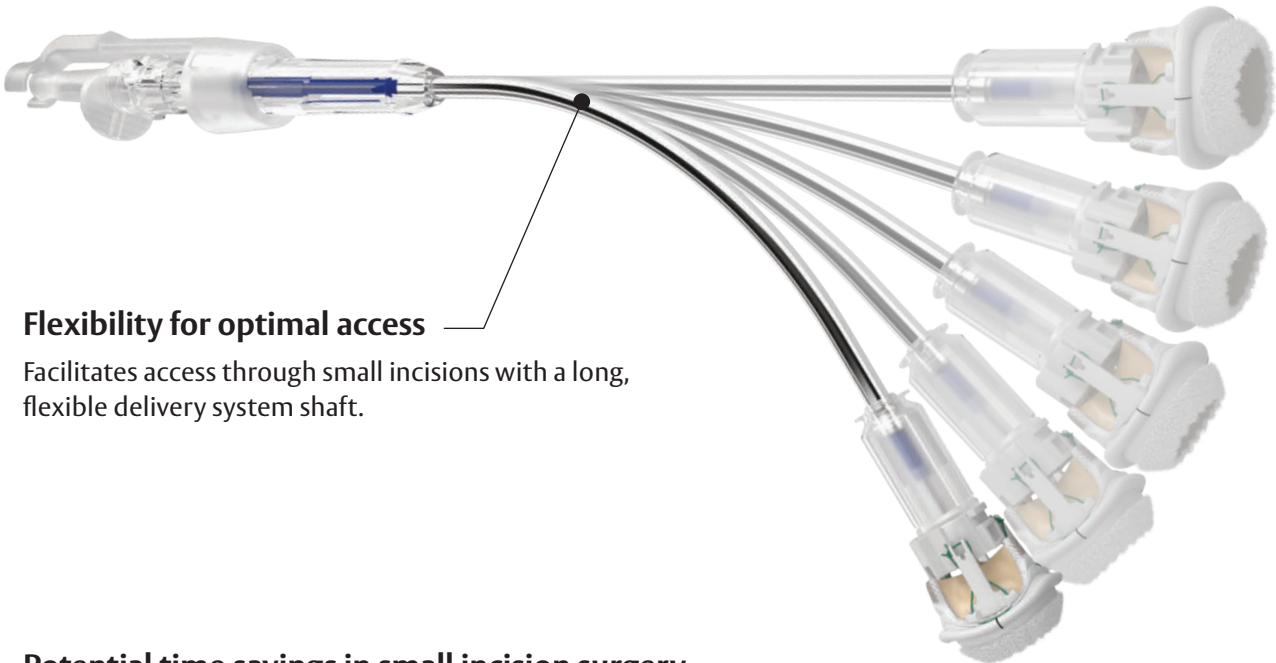
Utilizes a balloon expanded frame and 3 guiding sutures to provide ease of implantation and excellent visualization.

Traditional surgical valves

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



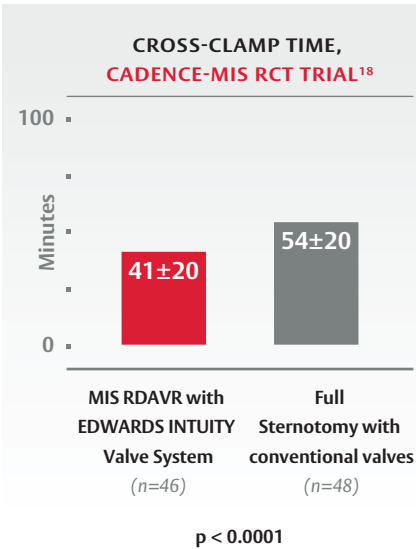
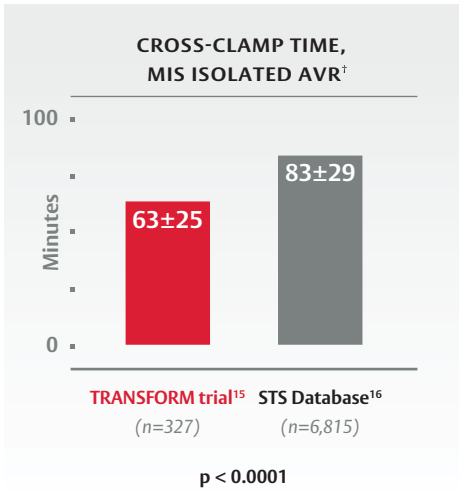
12–15 Sutures



Flexibility for optimal access

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

Potential time savings in small incision surgery

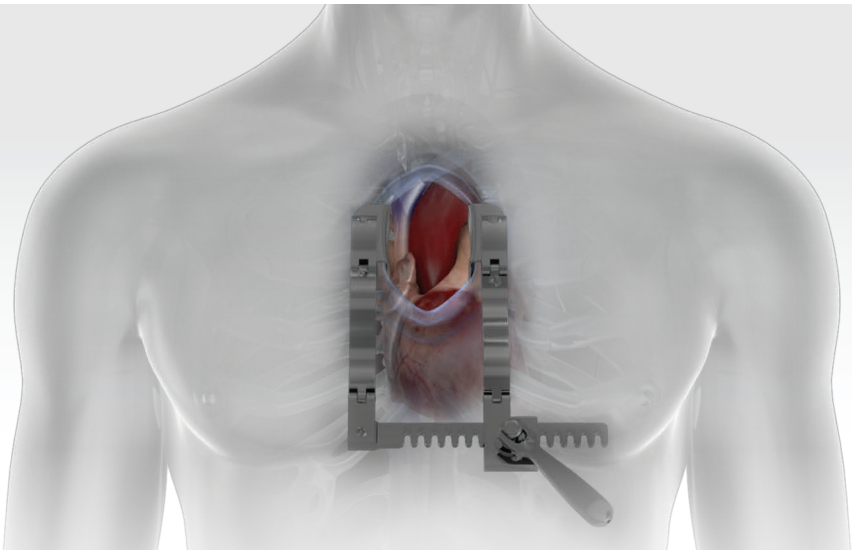


MIS with the EDWARDS INTUITY valve system showed 24% shorter cross clamp time versus full sternotomy with conventional valves.¹⁸

High use of small incision approaches

The TRANSFORM trial¹⁵ showed high rates of small incision usage in isolated AVR.

60%
(n=327/548)



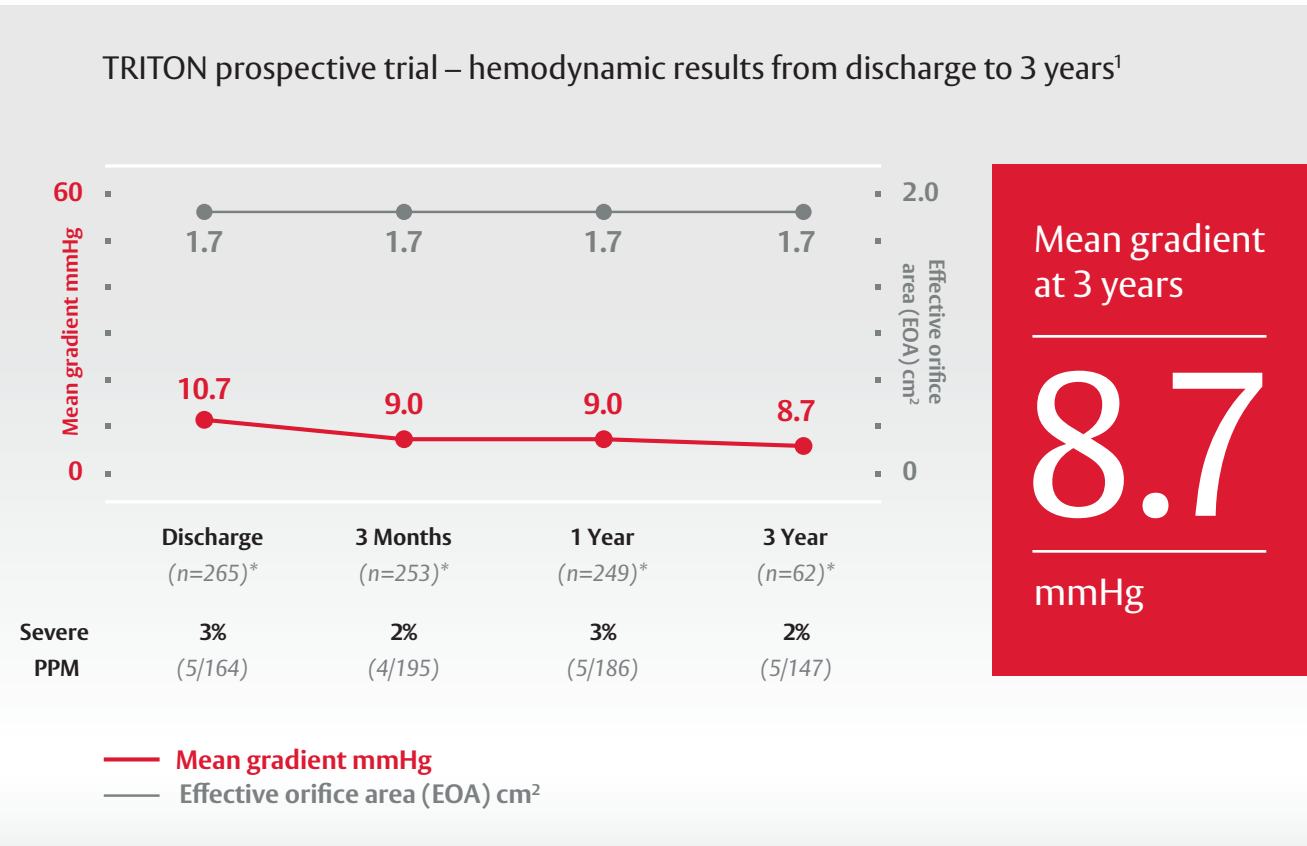
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Excellent hemodynamic performance

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.



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.





For more information visit
www.edwards.com/leadingtheevolution

Important Safety Information

EDWARDS INTUITY Elite valve system

Aortic Valve, Model 8300AB & delivery system, Model 8300DB

Indications: The EDWARDS INTUITY Elite valve is indicated for the replacement of diseased, damaged or malfunctioning native or prosthetic valves. **Contraindications:** The EDWARDS INTUITY Elite valve is contraindicated for use in patients with pure aortic insufficiency and aneurysms of the aortic root or ascending aorta. **Warnings:** The safety and effectiveness of the valve has not been studied in the following specific populations: patients who are pregnant or lactating; patients with chronic renal impairment or calcium metabolism disorders; patients with active endocarditis or myocarditis; or children or adolescents. As with any implanted device, there is potential for an immunological response. Use of the EDWARDS INTUITY Elite valve system may be associated with new or worsened conduction system disturbances, which may require a permanent pacemaker implant. **Potential Adverse Events:** Adverse events potentially associated with the use of bioprosthetic heart valves and aortic valve replacement surgery include but are not limited to: annulus damage, dissection, or tear; hemolysis; cardiac arrhythmias/conduction disturbances; congestive heart failure; endocarditis; leaflet impingement (aortic or mitral); myocardial infarction (MI); neurologic events; patient-prosthesis mismatch (PPM) (due to inappropriate sizing); reoperation or re-intervention, structural/non-structural valve dysfunction, explantation and death.

Additional potential risks associated with the use of a bioprosthetic valve with a reduced number of sutures similar to the EDWARDS INTUITY Elite valve include: valve leakage; paravalvular (perivalvular) leak; transvalvular regurgitation; valve stenosis; valve thrombosis; valve frame distortion (from chest compression or trauma); and valve malposition, instability, dislodgement or migration/embolization.

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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EDWARDS INTUITY Elite valve system

References and Important Safety Information



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References

1. Haverich A, Wahlers TC, Borger MA, et al. Three-Year Hemodynamic Performance, Left Ventricular Mass Regression, and Prosthetic-Patient-Mismatch After Rapid Deployment Aortic Valve Replacement in 287 Patients, *J Thorac Cardiovasc Surg.* 2014;148(6):2854-60
**These data pertain to an earlier generation EDWARDS INTUITY system and supported the CE Mark approval for the EDWARDS INTUITY Elite valve system.
2. Banbury MK, Cosgrove DM III, White JA, et al. Age and Valve Size Effect on the Long-term Durability of the Carpentier-Edwards Aortic Pericardial Bioprosthesis. *Ann Thorac Surg.* 2001;72(3):753-757. (Cohort size = 267, mean age = 65 ± 12 yrs. Number at risk for Explant for SVD at last follow-up not reported)
3. McClure RS, Narayanasamy N, Wiegerinck E, et al. Late Outcomes for Aortic Valve Replacement with the Carpentier-Edwards Pericardial Bioprosthesis: Up to 17-year Follow-up in 1,000 Patients. *Ann Thorac Surg.* 2010;89(5):1410-1416. (Cohort size = 1,000, mean age = 74.1 ± 0.29 yrs. Number at risk for SVD at last follow-up not reported)
4. Welke KF, Wu Y, Grunkemeier GL, Ahmad A, Starr A. Long-term results after Carpentier-Edwards pericardial aortic valve implantation, with attention to the impact of age. *The Heart Surgery Forum.* 2011;14(3):E160-165.
5. Minakata K et al. Long-Term Outcome of the Carpentier-Edwards Pericardial Valve in the Aortic Position in Japanese Patients. *Circulation Journal* 2014;78:882-889. (Cohort size = 574, mean age = 71.9 yrs. Number at risk for Structural Deterioration at 15-year follow-up = 54)
6. Jamieson WR, Germann E, Aupart MR, et al. 15-year Comparison of Supra-annular Porcine and PERIMOUNT Aortic Bioprostheses. *Asian Cardiovasc Thorac Ann.* 2006;14(3):200-205. (Cohort size = 1,430, mean age = 69.5 ± 10.4 yrs. Number at risk for SVD at last follow-up = 33)
7. Grunkemeier GL, Furnary AP, Wu Y, Wang L, Starr A. Durability of pericardial versus porcine bioprosthetic heart valves. *The Journal of Thoracic and Cardiovascular Surgery.* 2012;144(6):1381-1386.
8. Biglioli P, Spampinato N, Cannata A, et al. Long-term outcomes of the Carpentier-Edwards pericardial valve prosthesis in the aortic position: effect of patient age. *J Heart Valve Dis.* 2004;13(1):S49-51. (Cohort size = 327, mean age = 67.2 ± 10.6 yrs. Number at risk for Prosthesis Replacement at last follow-up not reported)
9. Bergoënd E, Aupart MR, Mirza A, et al. 20 years' durability of Carpentier-Edwards Perimount stented pericardial aortic valve. In: Yankah CA, Weng Y, Hetzer R, eds. *Aortic Root Surgery The Biological Solution.* Berlin: Springer; 2010:441-451. (Cohort size = 1,857, mean age = 69.8 yrs, Number at risk for Structural Valve Deterioration at last follow-up not reported)
10. Aupart MR, Mirza A, Meurisse YA, et al. Perimount Pericardial Bioprosthesis for Aortic Calcified Stenosis: 18-year Experience with 1133 Patients. *J Heart Valve Dis.* 2006;15(6):768-775. (Cohort size = 1,133, mean age = 72.6 yrs. Number at risk for SVD at last follow-up = 2)
11. Bourguignon T, et al. Very Long-Term Outcomes of the Carpentier-Edwards PERIMOUNT Valve in Aortic Position. *Ann Thorac Surg.* 2015 Mar;99(3):831-7. (Cohort size = 2,659, mean age = 71 ± 10.4 yrs. Number at risk for explant for Structural Valve Deterioration = 28).
12. Forcillo J et al. Carpentier-Edwards Pericardial Valve in the Aortic Position: 25-Years Experience. *Ann Thorac Surg* 2013;96:486-93. (Cohort size = 2,405, mean age = 71 yrs. Number at risk for Structural Deterioration at last follow-up = 30)
13. Clinical Communiqué. Carpentier-Edwards PERIMOUNT Aortic Pericardial Bioprosthesis 20-year Results. Data on file at Edwards Lifesciences, 2003. (Cohort size = 267, mean age = 65 ± 12 yrs. For patients ≥ 65, number at risk for explant due to SVD at last follow-up = 2)
14. Johnston DR, Soltesz EG, Vakil N, et al. Long-term durability of bioprosthetic aortic valves: implications from 12,569 implants. *Ann Thorac Surg.* 2015 Apr;99(4):1239-47. (Cohort size = 12,569, mean age = 71 ± 11 yrs. Number at risk for explant for Structural Valve Deterioration at 20 year follow-up = 54).
15. Clinical Investigation Report: Study Number; 2011-02 Report Date: 25 February 2016; TRANSFORM Database December 3, 2015.
16. STS database for the period of July 2011 - December 2012.
17. Al-Sarraf N, Thalib L, Houlihan M, Tolan M, Young V, McGovern E. Cross-clamp time is an independent predictor of mortality and morbidity in low- and high-risk cardiac patients. *Int J Surg* 2011;9:104-109
18. Borger MA, Dohmen P, Moustafine V, Conradi L, Knosalla C, Richter M, Merk DR, Doenst T, Hammerschmidt R, Treede H, Dohmen P, Strauch JT. Randomized Multi-Center Trial of Minimally Invasive Rapid Deployment Versus Conventional Full Sternotomy Aortic Valve Replacement (CADENCE-MIS). *The Annals of Thoracic Surgery*, 2014.
19. Clinical Investigation Report. Report Date: 07 June 2016; FOUNDATION Database February 1, 2016.

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