Leading the Evolution

Advanced approach on a proven platform

EDWARDS INTUITY Elite
Valve System

Edwards

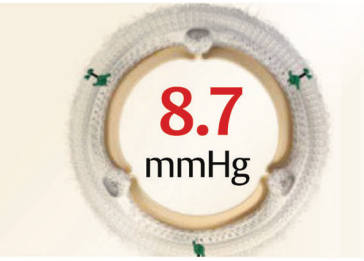
Evolution of a trusted design

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 patients[1]

Low supra-annular profile for maximum options

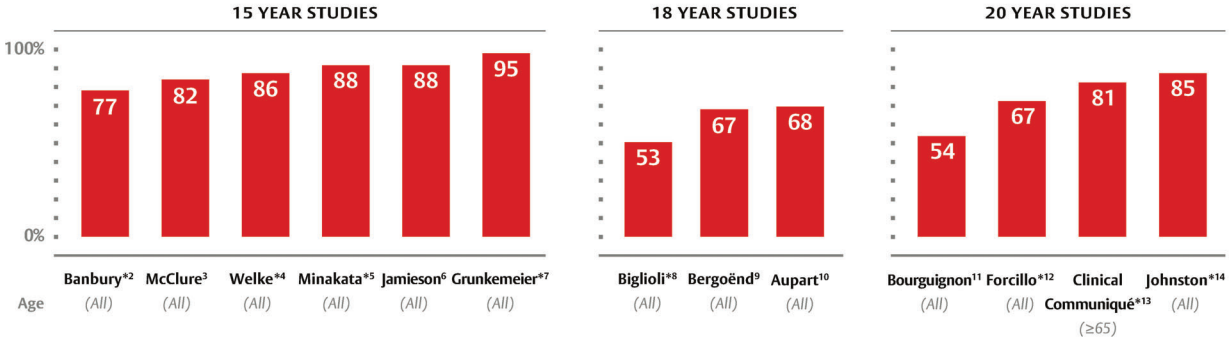
Low supra-annular profile facilitates use with any aortotomy and provides excellent clearance from the coronary ostia.

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.

Proven PERIMOUNT valve technology

New innovations

ThermaFix process†

Addresses both major calcium binding sites.

Matched Leaflets

Provides proven durability with three independent bovine pericardial leaflets matched for thickness and elasticity.

Flexible alloy wireform

Reduces loading shock on the leaflets during the cardiac cycle.

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 imp

Implantation of the EDWARDS
procedural steps.

Secure assembly

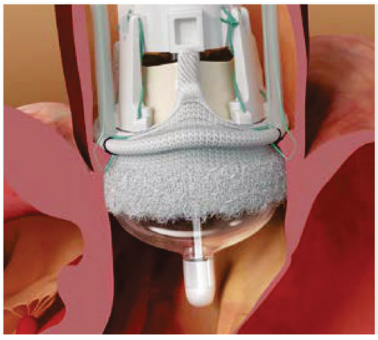
Engineered to ensure only the corre
valve and delivery system are conne
for procedural confidence.

Rapid valve preparation

No collapsing or folding of the valve
leaflets during preparation or implantatio

Innovative balloon design

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

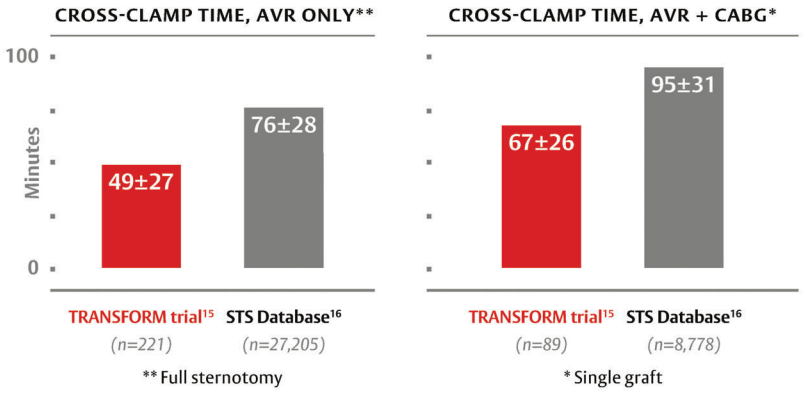


Balloon expanded delivery for efficient procedures

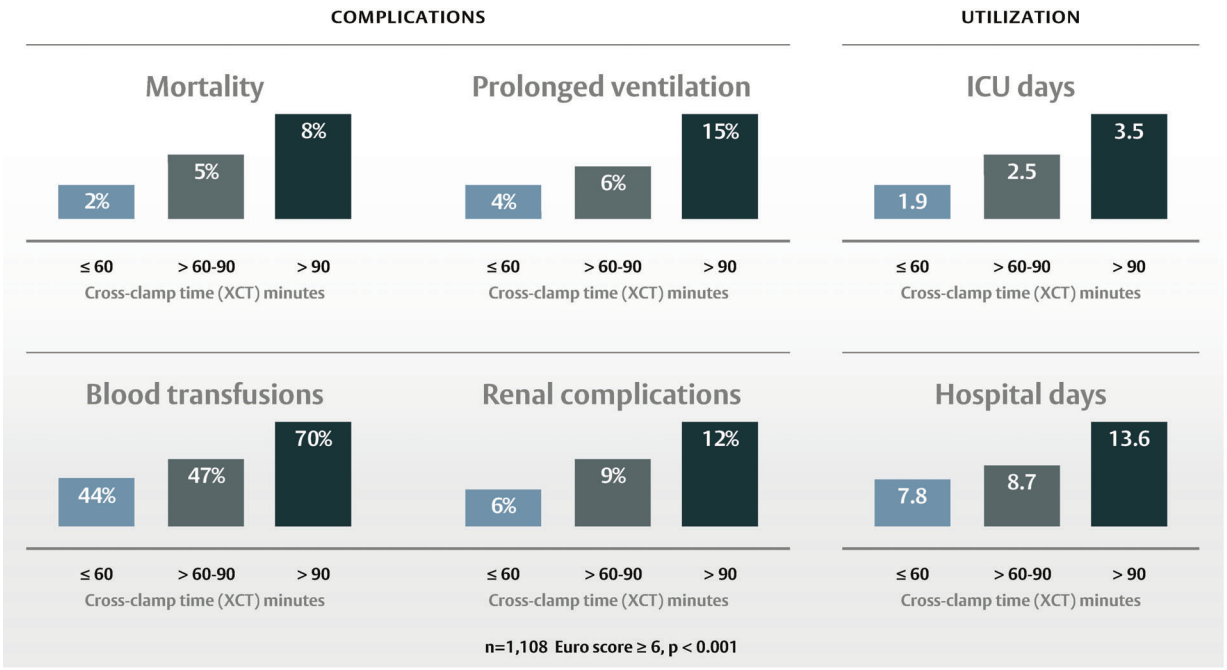
The EDWARDS INTUITY Elite valve system utilizes three guiding sutures in conjunction with the expanded frame for secure annular placement, helping reduce procedural steps.

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‡]



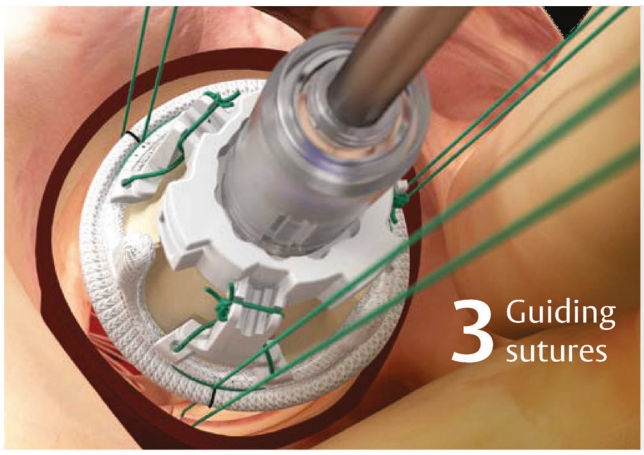
† Refer to Table 13 in the product's Instructions for Use

‡ 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.

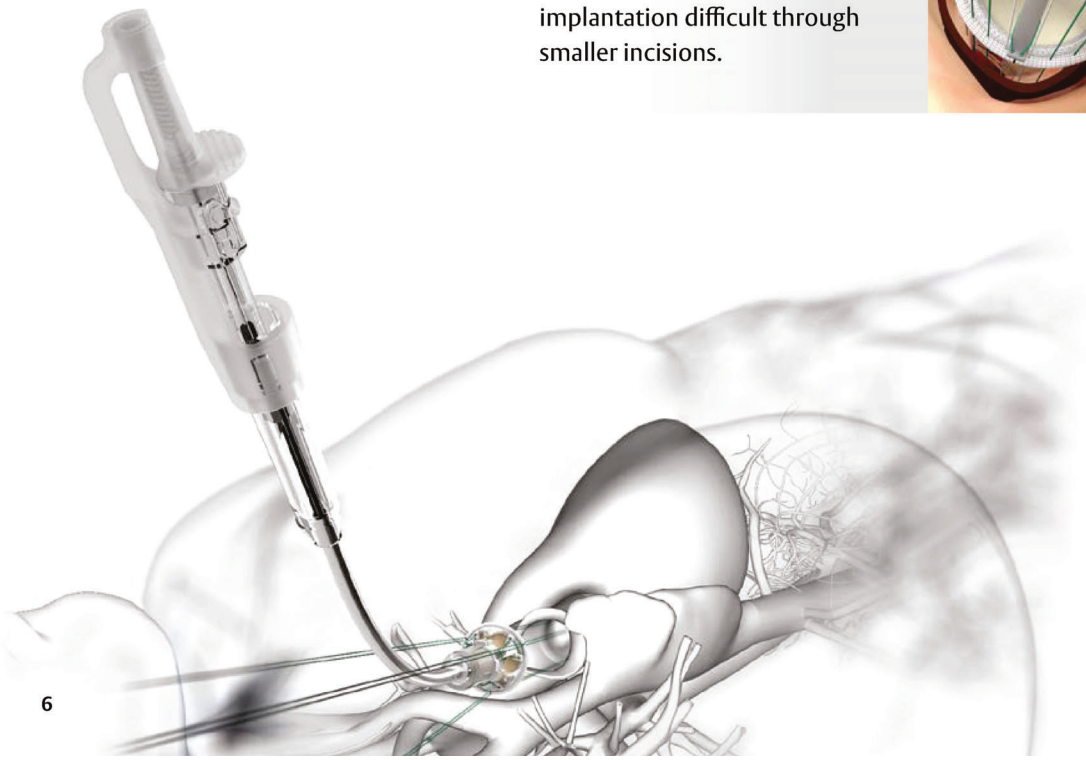


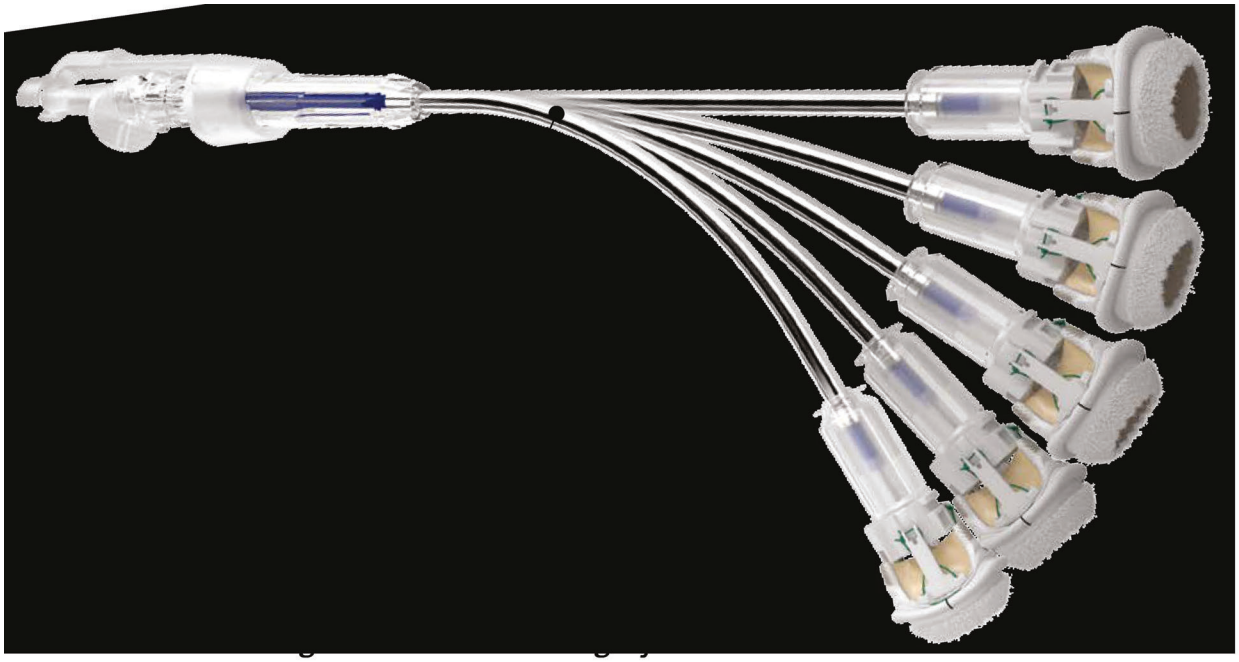
Streamlined delivery

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

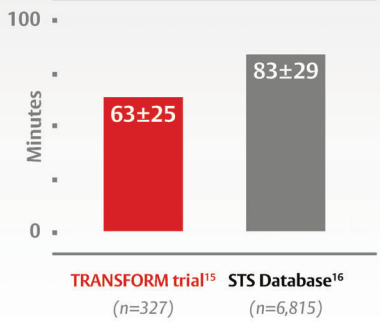
Traditional surgical valves

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



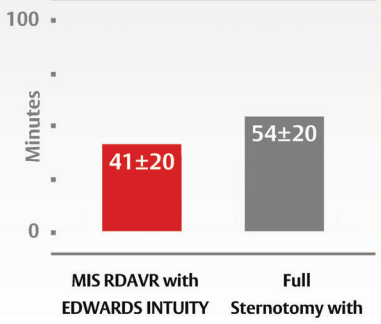


CROSS-CLAMP TIME, MIS ISOLATED AVR†



p < 0.0001

CROSS-CLAMP TIME, CADENCE-MIS RCT TRIAL[18]



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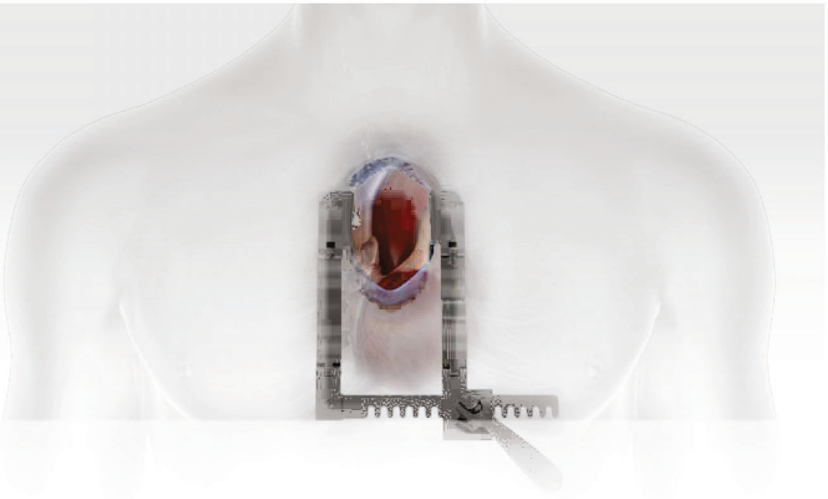
MIS with the EDWARDS INTUITY valve system showed 24% shorter cross clamp time versus full sternotomy with conventional valves.[18]

High use of small incision approaches

The TRANSFORM trial[15] showed high rates of small incision usage in isolated AVR.

60%

(n=327/548)



† 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.

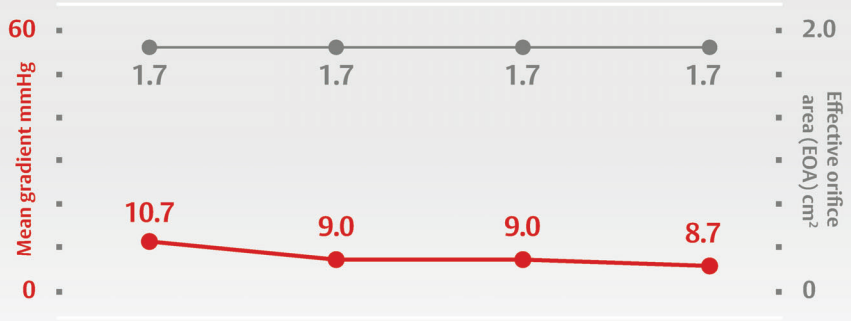
TRANSFORM Trial[15] – 1 year
10.3 mmHg

FOUNDATION Study[19] – 1 year
9.7 mmHg

CADENCE-MIS Trial[18] – 1 year
9.1 mmHg

In a large prospective trial[1], the EDWARDS INTUITY Elite valve demonstrated **excellent and stable hemodynamic performance** and significant LV mass regression out to 3 years.

TRITON prospective trial – hemodynamic results from discharge to 3 years[1]



	Discharge (n=265)*	3 Months (n=253)*	1 Year (n=249)*	3 Year (n=62)*
Severe PPM	3% (5/164)	2% (4/195)	3% (5/186)	2% (5/147)

Mean gradient at 3 years
8.7
mmHg

Mean gradient mmHg
Effective orifice area (EOA) cm²

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

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.

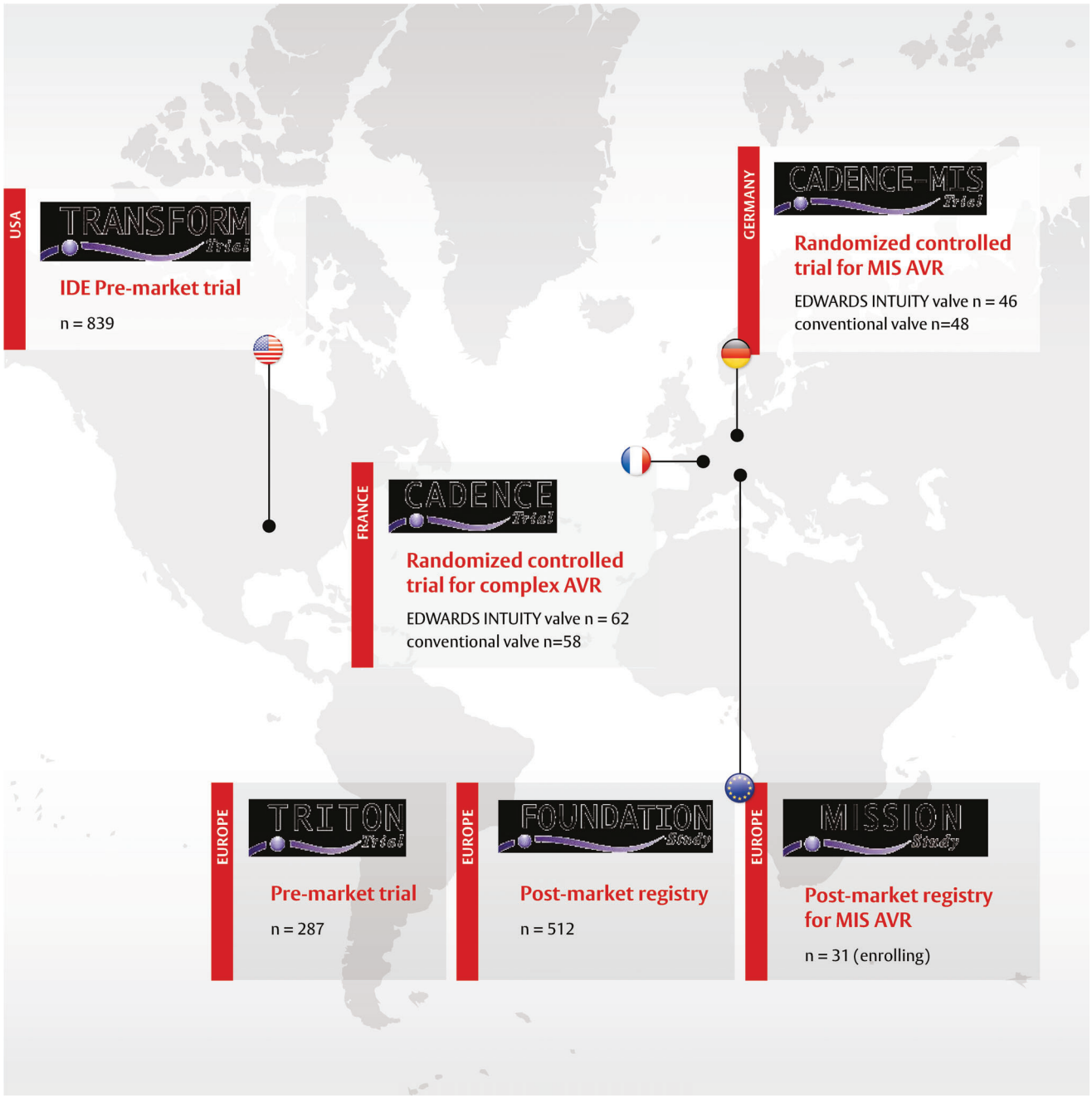
We have combined our **proven pericardial valve technology** with our **innovations in transcatheter heart valves** to create a new category of surgical valves designed to streamline procedures and facilitate smaller incision surgery. We believe more efficient, less invasive procedures can provide significant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

This is the next evolution of surgical aortic valves.

This is the EDWARDS INTUITY valve platform.

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.



▲ Important information enclosed

EDWARDS INTUITY Elite Valve System

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

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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References

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