Leading the Evolution

Advanced approach on a proven platform

EDWARDS INTUITY Elite
Valve System
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
† These data pertain to an earlier generation EDWARDS INTUITY valve as part of the TRITON trial.
Innovations

Proven PERIMOUNT valve technology

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.

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.1

CROSS-CLAMP TIME, AVR ONLY**

<table>
<thead>
<tr>
<th></th>
<th>TRANSFORM trial15</th>
<th>STS Database16</th>
</tr>
</thead>
<tbody>
<tr>
<td>(n=221)</td>
<td>49±27</td>
<td>76±28</td>
</tr>
</tbody>
</table>

** Full sternotomy

CROSS-CLAMP TIME, AVR + CABG*

<table>
<thead>
<tr>
<th></th>
<th>TRANSFORM trial15</th>
<th>STS Database16</th>
</tr>
</thead>
<tbody>
<tr>
<td>(n=89)</td>
<td>67±26</td>
<td>95±31</td>
</tr>
</tbody>
</table>

* Single graft

Shorter cross-clamp times generally lead to reduced complications and hospital utilization rates.7

### COMPLICATIONS

<table>
<thead>
<tr>
<th></th>
<th>≤ 60</th>
<th>&gt; 60-90</th>
<th>&gt; 90</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-operative mortality</td>
<td>2%</td>
<td>5%</td>
<td>8%</td>
</tr>
<tr>
<td>Post-operative prolonged ventilation</td>
<td>4%</td>
<td>6%</td>
<td>15%</td>
</tr>
</tbody>
</table>

### Utilization

<table>
<thead>
<tr>
<th></th>
<th>≤ 60</th>
<th>&gt; 60-90</th>
<th>&gt; 90</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU days</td>
<td>1.9</td>
<td>2.5</td>
<td>3.5</td>
</tr>
</tbody>
</table>

### Blood Transfusions

<table>
<thead>
<tr>
<th></th>
<th>≤ 60</th>
<th>&gt; 60-90</th>
<th>&gt; 90</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 60</td>
<td>44%</td>
<td>47%</td>
<td>70%</td>
</tr>
</tbody>
</table>

### Renal Complications

<table>
<thead>
<tr>
<th></th>
<th>≤ 60</th>
<th>&gt; 60-90</th>
<th>&gt; 90</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 60</td>
<td>4%</td>
<td>9%</td>
<td>12%</td>
</tr>
</tbody>
</table>

### Hospital days

<table>
<thead>
<tr>
<th></th>
<th>≤ 60</th>
<th>&gt; 60-90</th>
<th>&gt; 90</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 60</td>
<td>7.8</td>
<td>8.7</td>
<td>13.6</td>
</tr>
</tbody>
</table>

1 Refer to Table 13 in the product’s Instructions for Use

8 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

<table>
<thead>
<tr>
<th>CROSS-CLAMP TIME, MIS ISOLATED AVR</th>
<th>CROSS-CLAMP TIME, CADENCE-MIS RCT TRIAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRANSFORM trial (n=327)</td>
<td>MIS RDAVR with EDWARDS INTUITY Valve System (n=46)</td>
</tr>
<tr>
<td>63±25</td>
<td>41±20</td>
</tr>
<tr>
<td>STS Database (n=6,815)</td>
<td>Full Sternotomy with conventional valves (n=48)</td>
</tr>
<tr>
<td>83±29</td>
<td>54±20</td>
</tr>
</tbody>
</table>

\[ p < 0.0001 \]

MIS with the EDWARDS INTUITY valve system showed 24% shorter cross clamp time versus full sternotomy with conventional valves.\(^1\)

High use of small incision approaches
The TRITON trial\(^1\) and the TRANSFORM trial\(^15\) showed high rates of small incisions usages in isolated AVR.

58%\(^5\)
(n=414/706)

\(^1\) 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.

<table>
<thead>
<tr>
<th>Trial</th>
<th>1 year</th>
<th>Mean gradient mmHg</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRANSFORM trial(^{15})</td>
<td></td>
<td>10.3 mmHg</td>
</tr>
<tr>
<td>FOUNDATION study(^{19})</td>
<td></td>
<td>9.7 mmHg</td>
</tr>
<tr>
<td>CADENCE-MIS trial(^{18})</td>
<td></td>
<td>9.1 mmHg</td>
</tr>
</tbody>
</table>

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.

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.

---

\(^{*}\) 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.
References


3. McClure RS, Narayanasamy N, Wiegerink 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)


