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# TAVI ALLEGRA IMPERIA

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# Allegra Introduction



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HIGH SUCCESS RATE

LOW RATE OF COMPLICATIONS

HIGH SUCCESS RATE

LOW RATE OF COMPLICATIONS

STANDARD OF CARE



**ESC**

European Society  
of Cardiology

European Heart Journal (2025) **00**, 1–102

<https://doi.org/10.1093/eurheartj/ehaf194>

**ESC GUIDELINES**

# **2025 ESC/EACTS Guidelines for the management of valvular heart disease**

**Developed by the task force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)**

# Allegra

## Introduction



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TAVI is recommended in older patients ( $\geq 75$  years), or in those who are high risk (STS-PROM/EuroSCORE II  $> 8\%$ ) or unsuitable for surgery.

**I**

**A**

TAVI is recommended in patients  $\geq 70$  years of age with tricuspid AV stenosis, if the anatomy is suitable.

**I**

**A**

Trial	Age inclusion criteria	Mean age
PARTNER 3	None	73 years
Evolut Low Risk	None	74 years
DEDICATE-DZHK6	At least 65 years	74 years
NOTION-2	$\leq 75$ years of age	71 years

Age is key for risk estimation and a surrogate for life expectancy.

Age thresholds define trial population more clearly than life expectancy

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Introduction



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Easier

Safer

Long-term



# Allegra Stent



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- **Short, self-expandable stent**
- **6 Gold radiopaque markers** allow for perfect visibility and precise implantation
- **Three connecting bars in T-form**, facilitate safe anchoring to the catheter.
- **Different radial force to remove stress from leaflets**

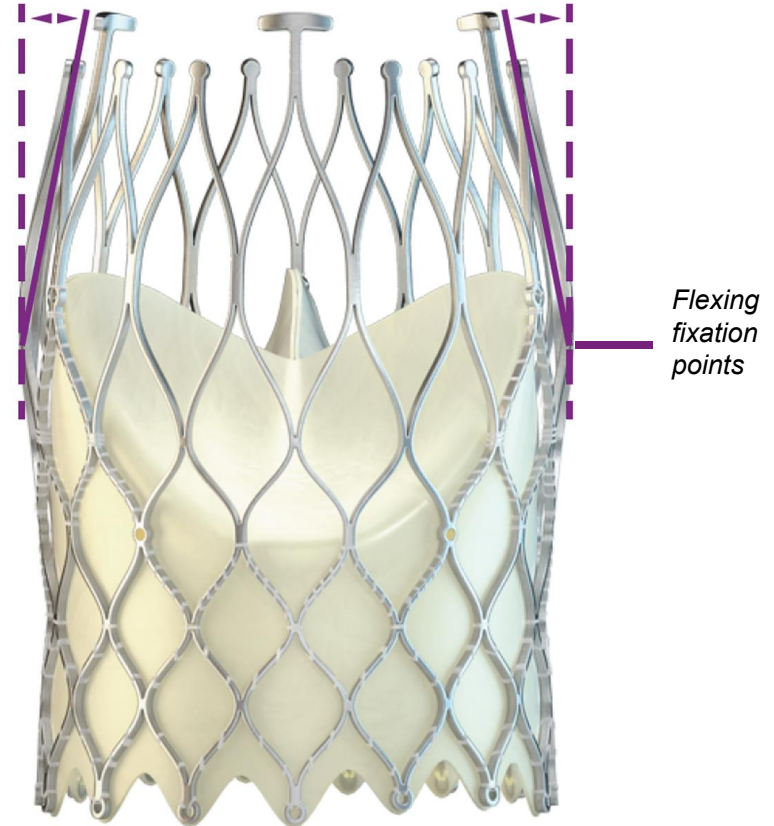


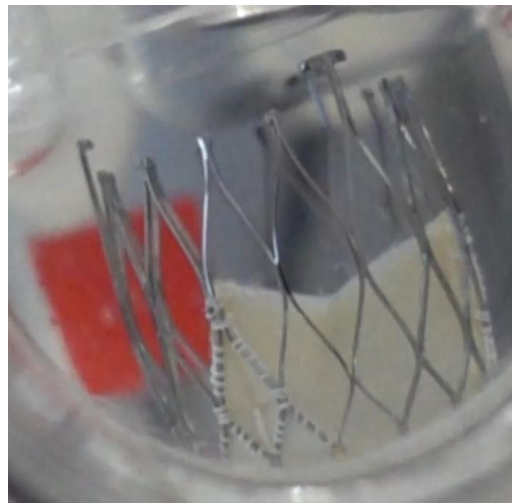


- 100% **bovine pericardium**; offers the longest follow up in literature
- **Tri-leaflet & Supra-annular** design
- **12 mm sealing area** minimizes the risk of paravalvular leakage

- The ALLEGRA™ stent frame allows for **flexing at the commissural fixation points**.
- In this way **the stress** to the leaflets in every cardiac cycle **is reduced** and the durability could be increased.

DURABILITY

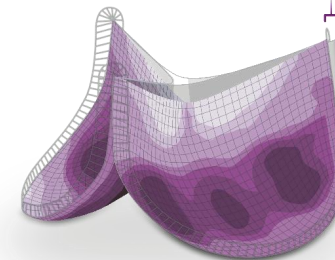




## POLE MOVEMENT



*Stent frame allows pole movement*



*Stent tip deflection during cardiac cycle*

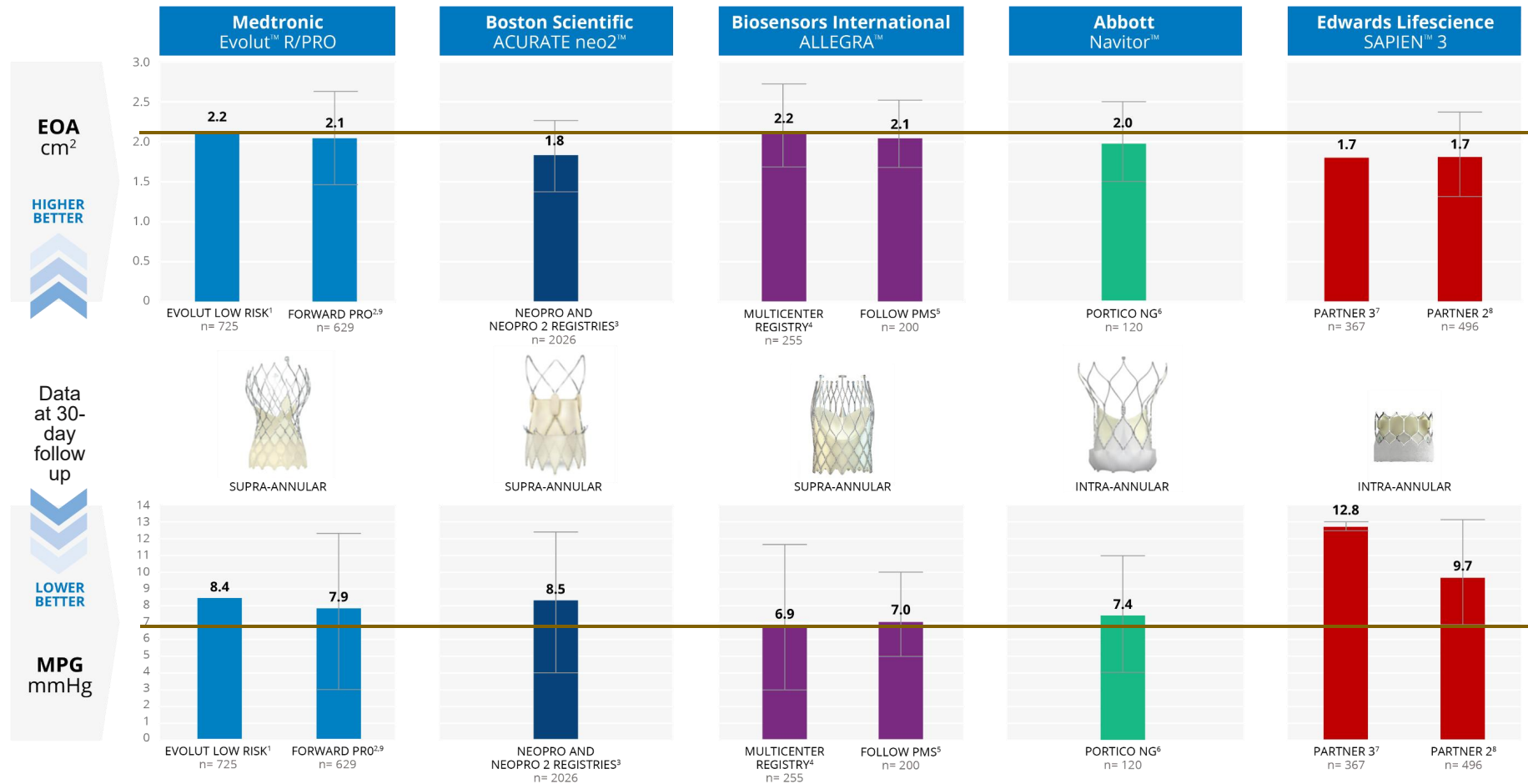
Physiological flow pattern in in-vitro test resulting in a longer lasting valve.

This translates in:

- Lower gradients,
- Less platelet activation,
- Hemolysis,
- Minimal paravalvular leak

## FLOW DYNAMICS





References: 1. EVOLUT LOW RISK: J.J. Popma et al. - Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients – NEJM 2019 - DOI: 10.1056/NEJMoa1816885; 2. FORWARD PRO: G. Manoharan et al. - Thirty-day clinical outcomes of the Evolut PRO self-expanding transcatheter aortic valve: the international FORWARD PRO study – Eurointervention 2020 - DOI: 10.4244/EIJ-D-20-00279; 3. NEOPRO AND NEOPRO 2 REGISTRIES: A. Scotti et al. - Haemodynamic performance and clinical outcomes of transcatheter aortic valve replacement with the self-expanding ACURATE neo2 – Eurointervention 2022 - DOI: 10.4244/EIJ-D-22-00289; 4. Multicenter Registry: M. Wolfrum - The Allegra transcatheter heart valve: Short term results from a multicenter registry - Catheter Cardiovasc Interv. 2021 - DOI: 10.1002/ccd.29833; 5. FOLLOW PMS: Clinical outcomes of the NVT ALLEGRA TAVI System TF in failing calcified aortic heart valves in a real-world patient population with elevated surgical risk – Clinical Report; 6. PORTICO NG: L. Sondergaard et al. - Thirty-day and one-year outcomes of the Navitor transcatheter heart valve in patients with aortic stenosis: the prospective, multicentre, global PORTICO NG Study – Eurointervention 2023 - DOI: 10.4244/EIJ-D-22-01108; 7. PARTNER 3: M.J. Mack - Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients – NEJM 2019 - DOI: 10.1056/NEJMoa1814052; 8. PARTNER 2: M.B. Leon - Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients – NEJM 2016 - DOI: 10.1056/NEJMoa1514616; 9. Data at discharge.

# Allegra Valve

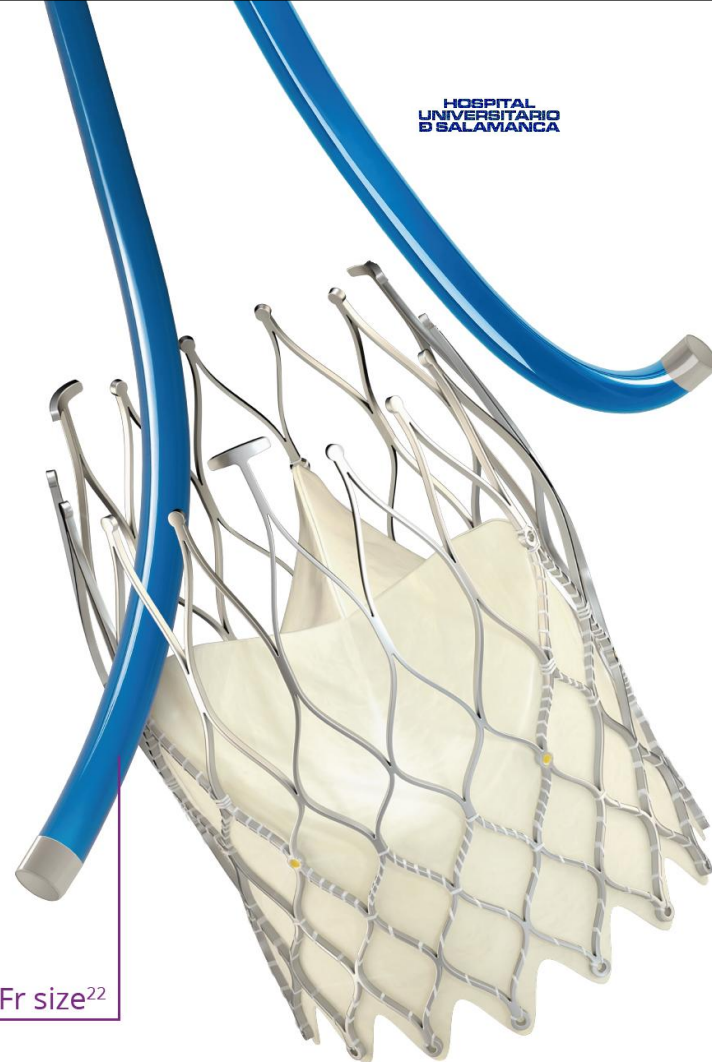
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ALLEGRA™ maintains access to the coronary ostia for future coronary interventions.

The 6 radiopaque gold markers highlight where the top of the sealing skirt is and ensures precise implantation for future coronary access.

CORONARY ACCESS

Up to 12 Fr size<sup>22</sup>



# Allegra Delivery system



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- Usable length 1150 mm, 18 Fr Cartridge / 15 Fr Catheter, Gradual decrease in stiffness
- **PermaFlow deployment** – Constant flow during implantation
- **Squeeze-to-Release mechanism** allows for stepwise and controlled implantation avoiding rotation
- Optimized catheter tip design enables an atraumatic implantation
- Safety locker mechanism guarantees a safe release



> J Invasive Cardiol. 2023 Dec;35(12). doi: 10.25270/jic/23.00163.

## The Allegra transcatheter heart valve: Long-term clinical and echocardiographic outcomes

**103** patients

Mean gradient was  $7.7 \pm 3.3$  mmHg  
EOA was  $2.0 \pm 0.5$  cm<sup>2</sup>  
1-year follow-up

14.7% new permanent  
pacemaker

More than mild PVL  
3.3% at 1 year

No thrombosis, structural-valve-deterioration (SVD), or non-SVD occurred



# ALLOW study (Cruz-Gonzalez I, et al. CCI. 2025 under review)

**500** patients

96.8% success rate

Mild or less PVL  
95.9%

Gradient post implant  
4.0 mmHg



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Imperia

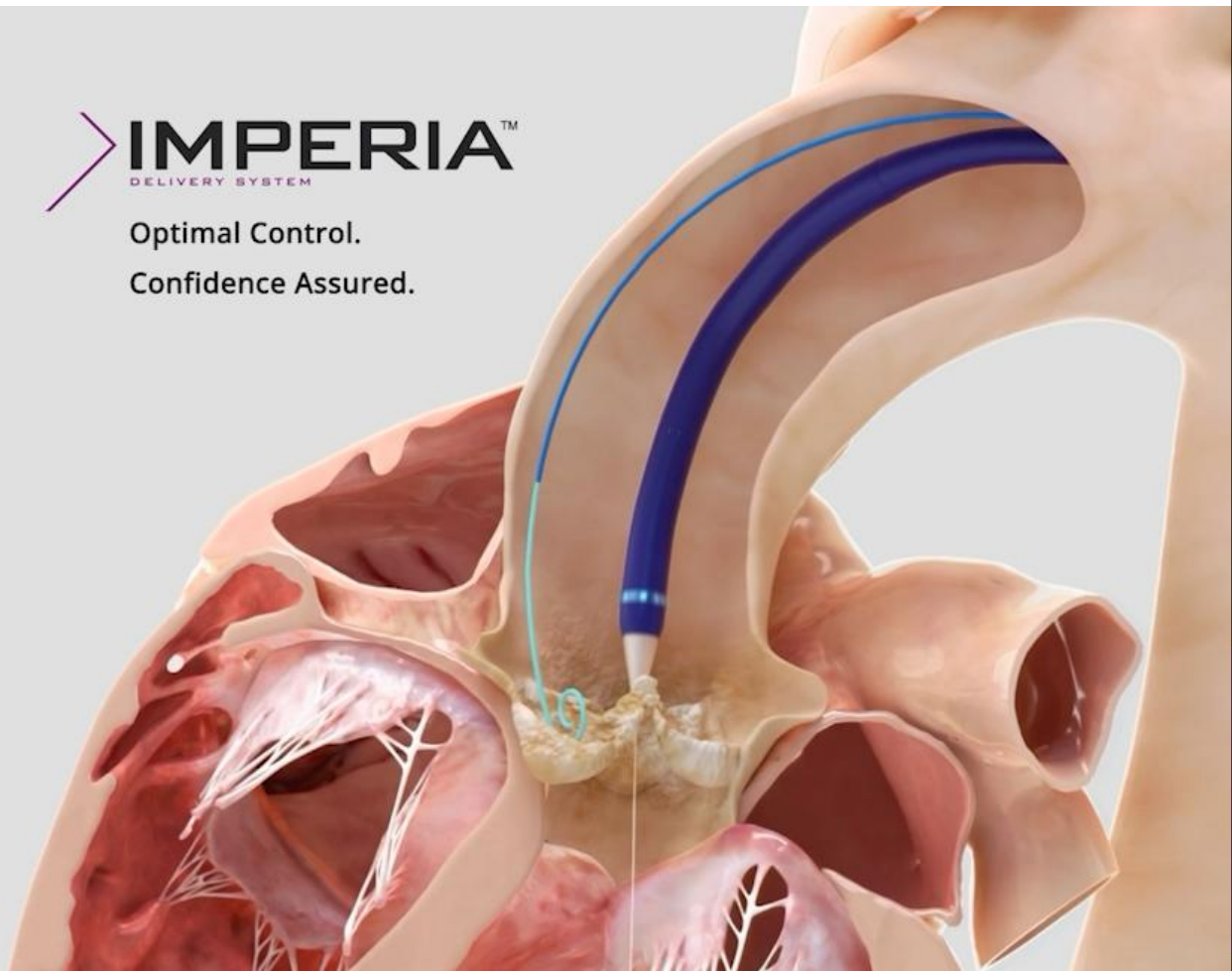


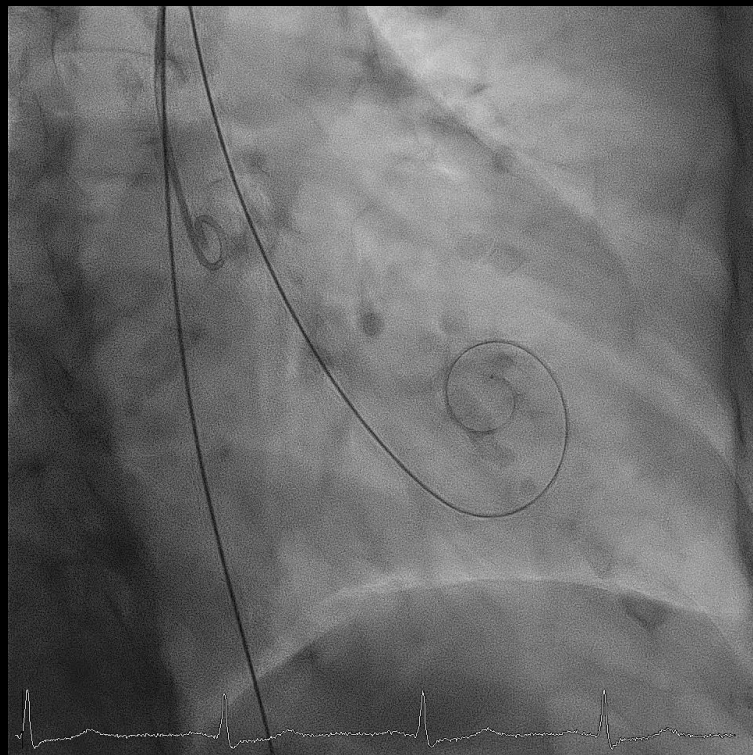
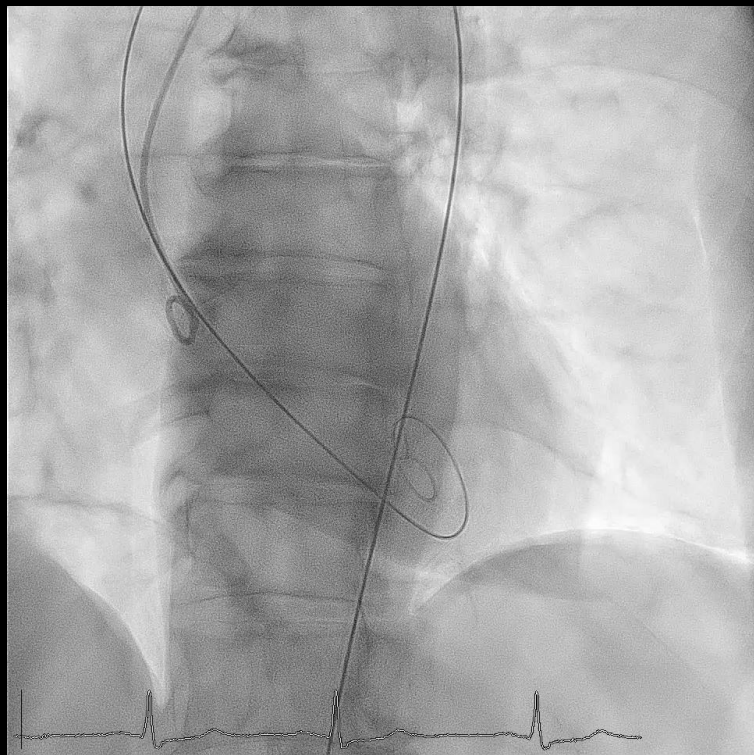
- Re-sheathable, repositionable and fully-retrievable
- Self-locking winding mechanism
- Highly flexible 15F catheter with 18F capsule
- Hydrophilic coating
- Same outer diameter for all 3 valve sizes



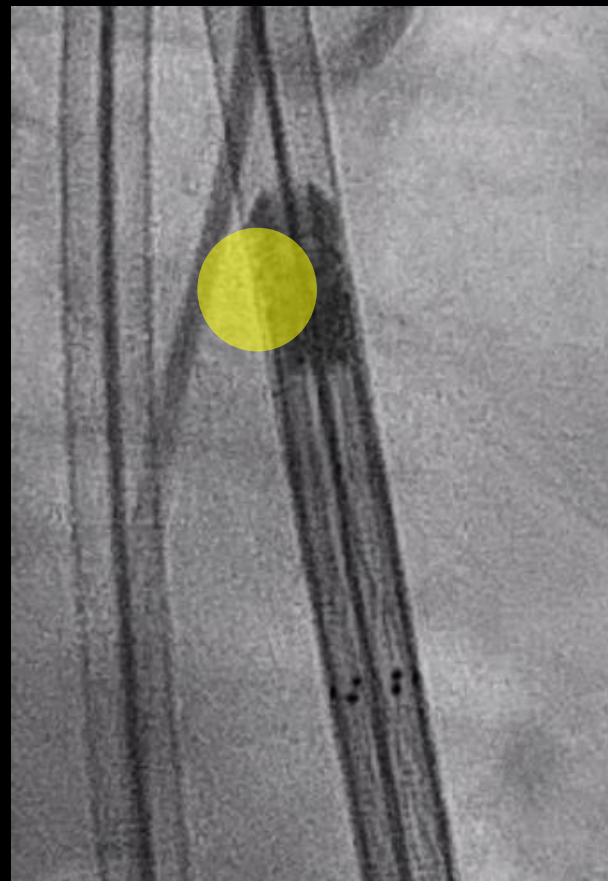
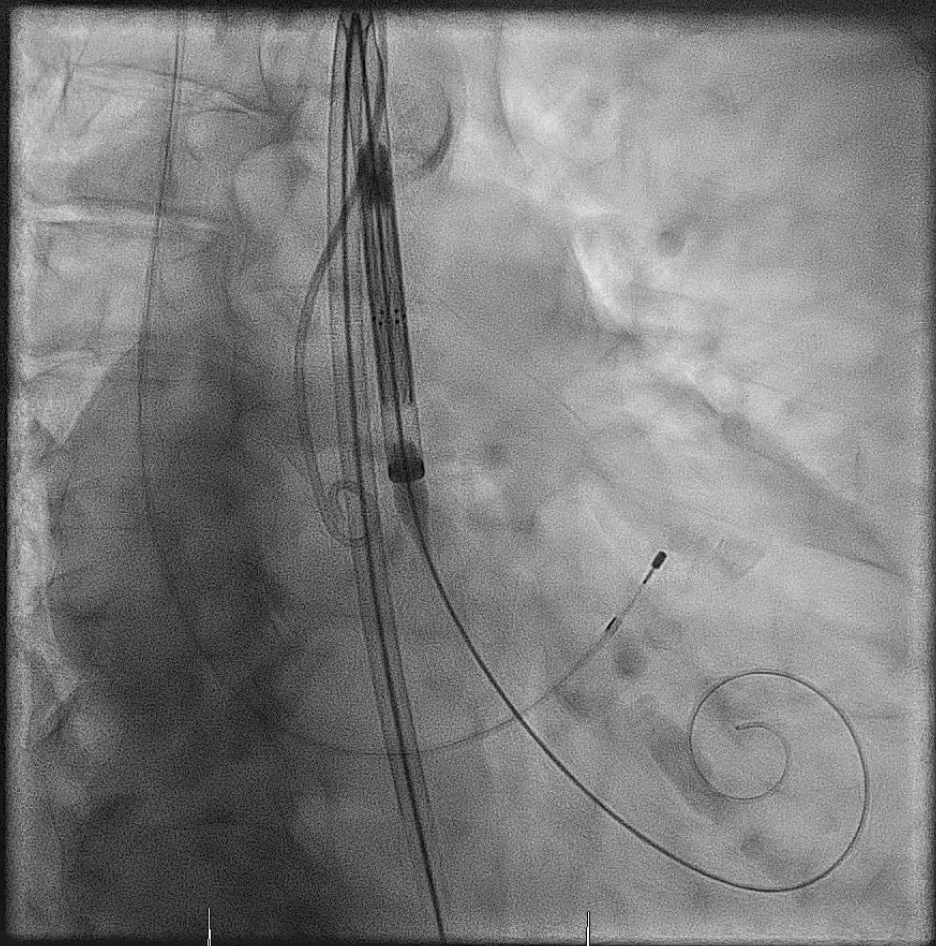
# **IMPERIA™** DELIVERY SYSTEM

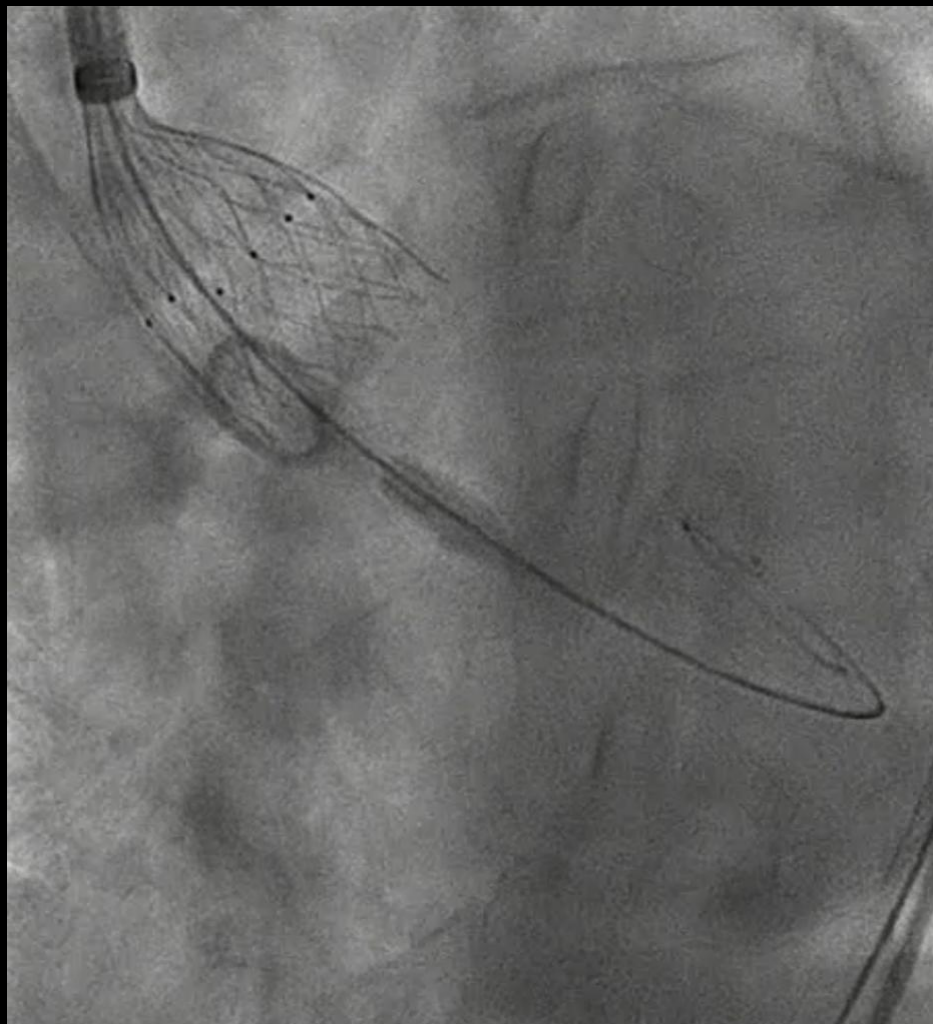
Optimal Control.  
Confidence Assured.

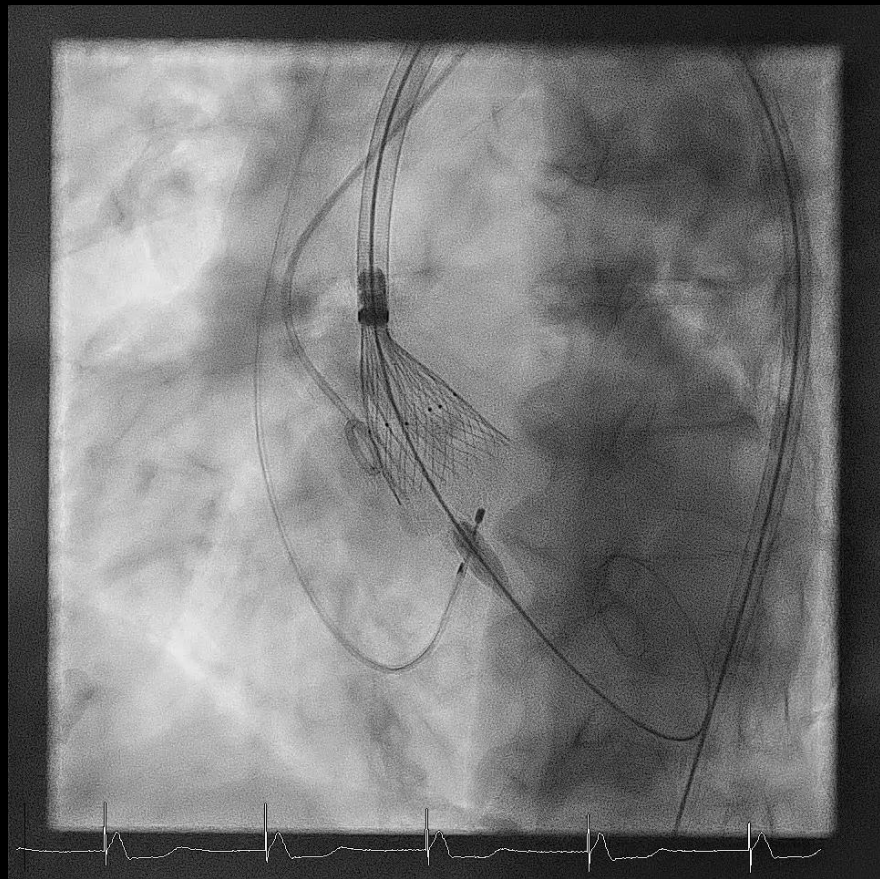
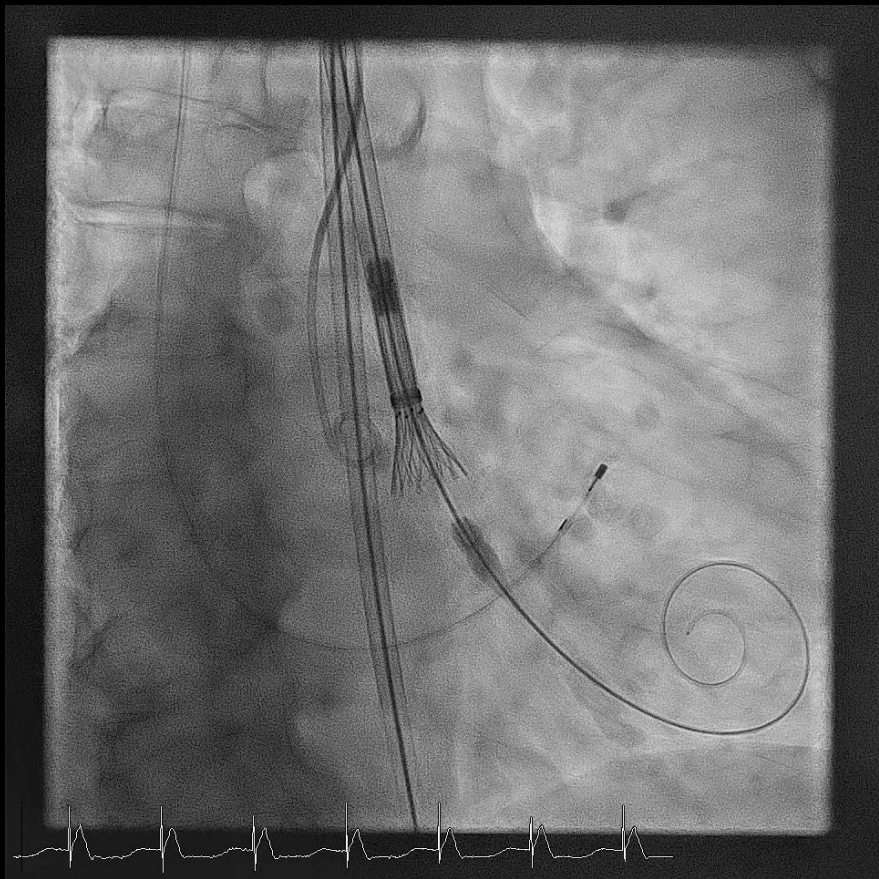




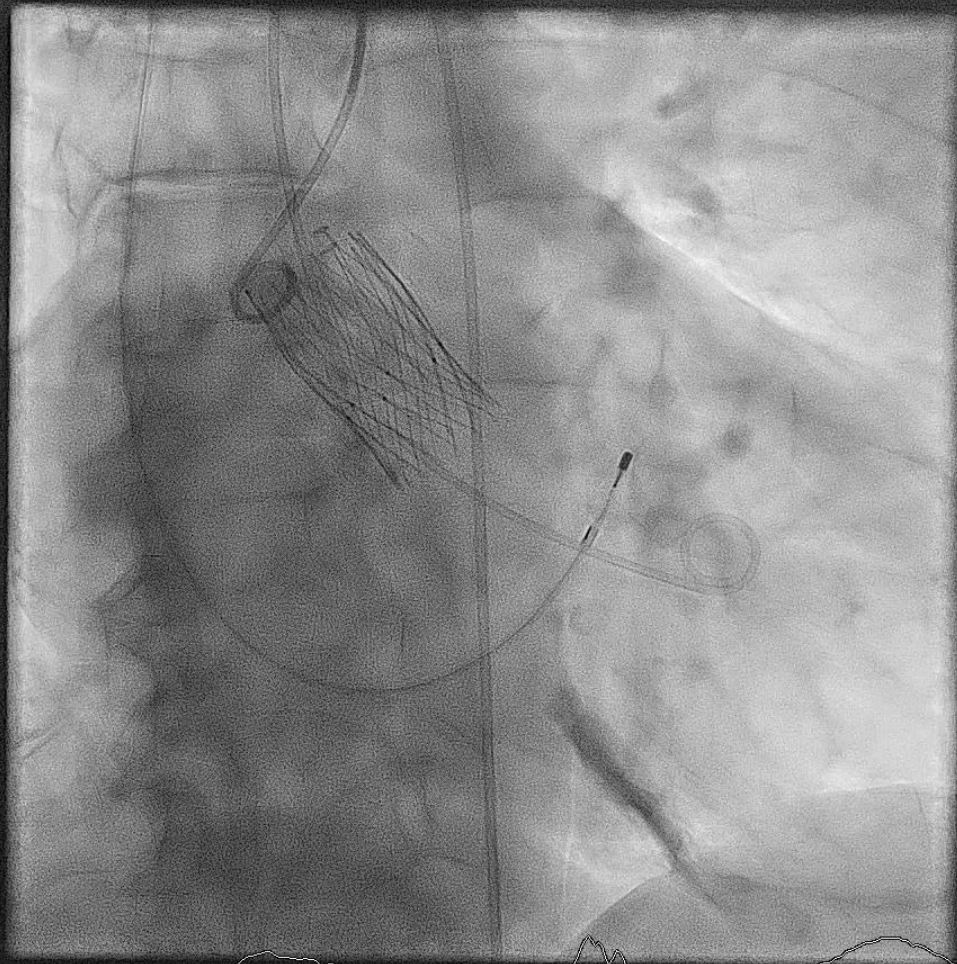












Gradient 3.6 mmHg  
Mild PVL

***SHOW ME  
THE  
DATA***

> Struct Heart. 2025 Feb 6;9(4):100391. doi: 10.1016/j.shj.2024.100391. eCollection 2025 Apr.

## **First-In-Human Experience of the New Fully Repositionable IMPERIA Delivery System to Implant the ALLEGRA Transcatheter Heart Valve in Patients With Severe Calcific Aortic Stenosis or Degenerated Surgical Bioprosthesis: Thirty-Day Results of the EMPIRE I Study**

José Antonio Baz <sup>1</sup>, Christof Burgdorf <sup>2</sup>, Christian Frerker <sup>3</sup>, Ignacio Cruz González <sup>4</sup>, Joan Antoni Gómez <sup>5</sup>, Joseph Graham <sup>6</sup>, José María Hernández <sup>7</sup>, Pilar Jiménez <sup>8</sup>, Claire B Ren <sup>9 10</sup>, Ernest Spitzer <sup>10</sup>, Pim Tonino <sup>11</sup>, Pieter Vriesendorp <sup>12</sup>, Nicolas van Mieghem <sup>9</sup>, Samuel Copt <sup>13</sup>, Anders Jönsson <sup>13</sup>, Keith G Oldroyd <sup>13</sup>, Nicolas Doll <sup>14</sup>

**137** patients (16 ViV)

99.3% success rate

No device embolizations

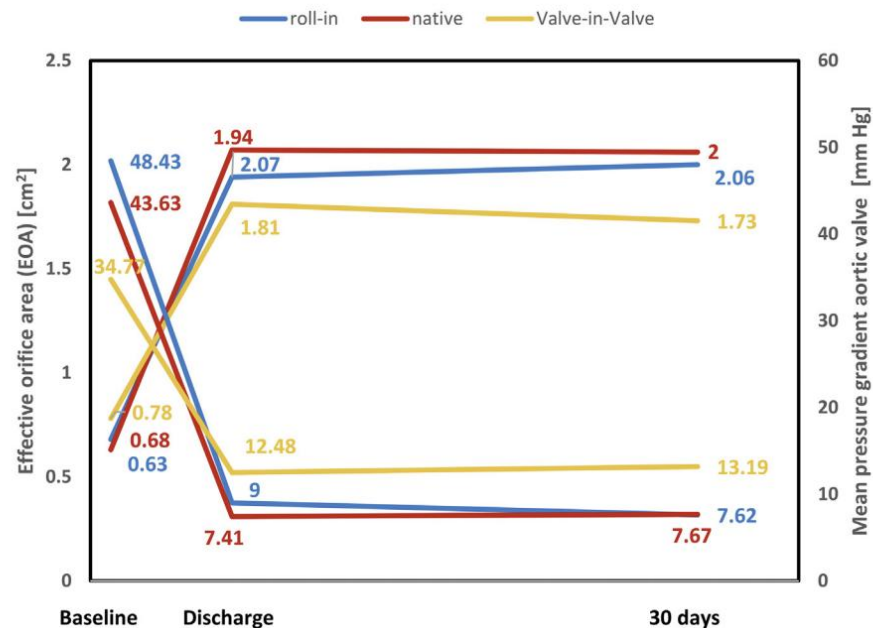
12.4% pacemaker implantation

No patient prosthesis mismatch

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# Conclusion

People don't use a product because of the great  
design,  
great design helps them to use the product.

