

# INSPIRIS RESILIA

## aortic valve

Master deck  
Version 2.0



Edwards

## Version updates

- In this version of the INSPIRIS RESILIA aortic valve clinical deck, the following updates have been made:
  - Up-to-date literature has been added to the section '[RESILIA tissue and INSPIRIS RESILIA aortic valve literature review](#)'
  - Updated [table of contents](#)
  - A new section '[Annex](#)' has been added to feature [reviews](#), [valve-in-valve](#) and [special cases](#)
  - New [Annex table of contents](#)
    - The new articles have been summarised on slides 67–78
    - The new annex articles have been summarised on slides 82–96
    - The relevant new [references](#) (97–99) and [abbreviations](#) (100) have been added

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# Introduction



Edwards



## Aortic valve replacement in aortic stenosis



### Surgical AVR is a fundamental intervention for severe aortic stenosis

- Improves symptoms and long-term survival<sup>1</sup>
- Shows good functional improvement and survival, even in elderly patients with comorbidities<sup>2,3</sup>



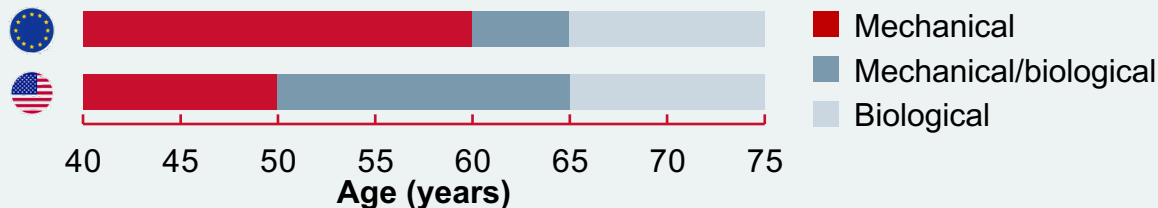
### Two options for replacement aortic valves are available<sup>4</sup>

- **Mechanical valves** are more durable than bioprosthetic valves, but they carry higher clotting risk. Therefore, patients must take anticoagulants for the rest of their lives, leading to a higher risk of bleeding
- **Biological valves** have lower thrombotic risk than mechanical valves, so patients do not require lifelong anticoagulation. However, the lower durability of biological valves gives them a higher reoperation risk



# Guideline recommendations for the treatment of valvular heart disease

Age recommendations based on the 2020 ACC/AHA and 2021 ESC/EACTS guidelines<sup>1,2</sup>



2020 ACC/AHA and 2021 ESC/EACTS guidelines<sup>1,2</sup>

- **Class I recommendation:** prosthetic valve choice should be based on shared decision-making
- Patient values and preferences must be taken into account

2020 ACC/AHA guidelines<sup>1</sup>

- **Class IIa recommendation:** for patients aged 50–65 years, individual factors should be considered alongside informed shared decision-making

2021 ESC/EACTS guidelines<sup>2</sup>

- **Class IIa recommendation:** for patients 60–65 years, both mechanical and biological valves are acceptable. The decision should be based on factors other than age

# INSPIRIS RESILIA valve builds upon the trusted Carpentier-Edwards PERIMOUNT aortic valve design



**Carpentier-Edwards  
PERIMOUNT valve<sup>1</sup>**  
Model 2800TFX

Bioengineered  
Flexible cobalt–chromium  
alloy stent  
Pericardial leaflets  
ThermaFix<sup>†</sup> treated



**Carpentier-Edwards  
PERIMOUNT Magna  
valve<sup>2</sup>**  
Model 3000\*

**Supra-annular design**  
**Upsize potential**  
Bioengineered  
Flexible cobalt–chromium  
alloy stent  
Pericardial leaflets



**Carpentier-Edwards  
PERIMOUNT Magna  
Ease valve<sup>2</sup>**  
Model 3300TFX

**Lower profile**  
**Ease of implant**  
**Supra-annular design**  
**Upsize potential**  
Bioengineered  
Flexible cobalt–chromium  
alloy stent  
Pericardial leaflets  
ThermaFix<sup>†</sup> treated



**INSPIRIS RESILIA  
aortic valve<sup>3</sup>**  
Model 11500A

**Lower profile**  
**Ease of implant**  
**Supra-annular design**  
**VFit technology<sup>‡</sup>**  
Bioengineered  
Flexible cobalt–chromium  
alloy stent  
Pericardial leaflets  
RESILIA tissue<sup>†</sup>

\*This model is no longer available; †No clinical data are available that evaluate the long-term impact of the Edwards Lifesciences tissue treatments in patients; ‡Refer to device 'Instructions for Use' for important warnings related to VFit technology. These features have not been observed in clinical studies to establish the safety and effectiveness of the model 11500A for use in valve-in-valve procedures

1. Carpentier-Edwards PERIMOUNT RSR Pericardial Aortic Bioprosthesis Model 2800TFX. Instructions for Use. 2006; 2. Edwards Lifesciences. Surgical aortic pericardial valves. Available at: [Surgical aortic pericardial valves | Edwards Lifesciences](#) [Accessed 25 November 2021]; 3. Edwards Lifesciences INSPIRIS RESILIA aortic valve. Model 11500a. Instructions for Use. 2020

# PERIMOUNT valve safety and long-term performance have been assessed in over 30 studies for up to 25 years of follow-up



Durability



Safety



Comparative study



## Bourguignon *et al.*<sup>1</sup>

N=2,659; mean age: 71 ± 10 years;  
mean follow-up: 7 ± 5 years

- Valve-related events: low incidence at 20 years
- Expected valve durability\*: **19.7 years**



## Forcillo *et al.*<sup>2,3</sup>

N=2,405; mean age: 71 ± 9 years;  
mean follow-up: 6 ± 9 years

- PERIMOUNT valve is **secure and durable**
- In patients aged <60 years, freedom from valve dysfunction: 5 years **97 ± 2%**, 10 years **84 ± 4%**, 15 years **57 ± 6%**



## Johnston *et al.*<sup>4</sup>

N=12,569; mean age: 71 ± 11 years;  
median follow-up: 6 years

- Durability confirmed in older patients
- In patients aged <60 years, freedom from explant for SVD at 20 years: **55%**

\*Calculated by median survival time



# PERIMOUNT Magna and Magna Ease valves' mid-term outcomes have been assessed in almost 6,000 patients



Durability



Safety



Comparative study



## Anselmi *et al.*<sup>1</sup>

N=849; mean age: 74 ± 9 years;  
mean follow-up: 4 ± 2 years

- Magna Ease valve freedom from SVD at 5 years: **99 ± 0.5%**
- PPM in smaller valves is not associated with mid-term mortality or worse functional class



## Theologou *et al.*<sup>2</sup>

N=699; median age: 74 years;  
median follow-up: 7 years

- Propensity-matched Magna valve vs Mitroflow valve at 10 years
- All-cause mortality lower in Magna valve cohort (**15% vs 35%**)
- Aortic valve reintervention lower in Magna valve cohort (**1% vs 5%**)



## Lam *et al.*<sup>3</sup>

N=923; mean age: 71 ± 8 years;  
mean follow-up: 4 ± 2 years

- Magna Ease valve cohort had a higher rate of event-free survival (**99.3%**) than Trifecta valve (95%) or Mitroflow valve (94%) cohorts



## Biancari *et al.*<sup>4</sup>

N=1,365; mean age: 74 ± 7 years;  
mean follow-up: 4 ± 2 years

- At 7 years, Magna Ease valve cohort had a lower risk of reintervention due to SVD (**0%**) compared with the Trifecta valve cohort (3.3%)

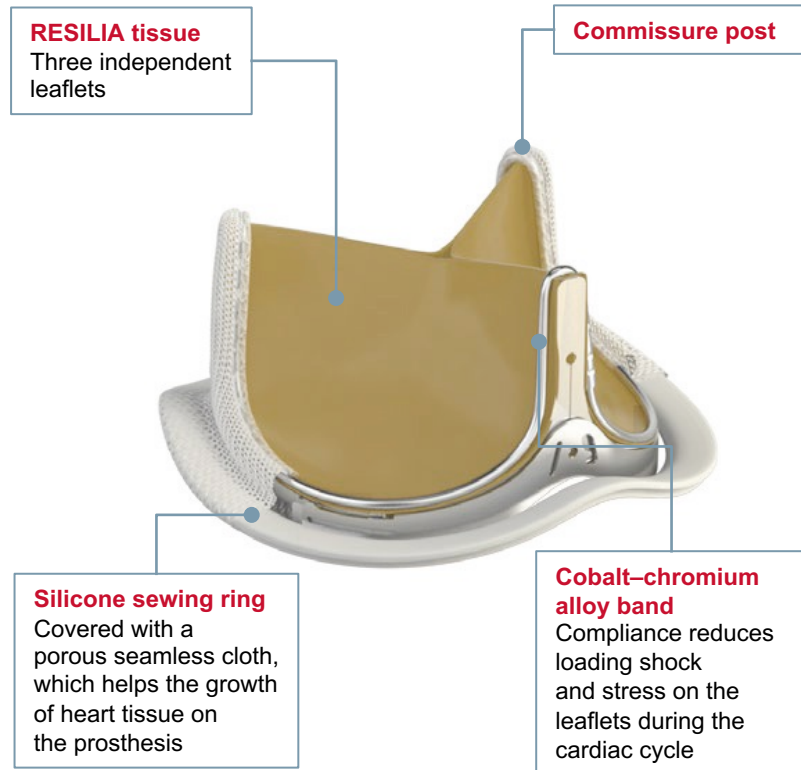


## Piperata *et al.*<sup>5</sup>

N=2,148; median age: 69–69.7 years;  
median follow-up: 4.5 years

- 12-year survival was **81%** for patients <65 years *versus* **45%** for those ≥65 years ( $p < 0.001$ )
- Age was an independent risk factor for the incidence of SVD

# INSPIRIS RESILIA aortic valve (model 11500A)



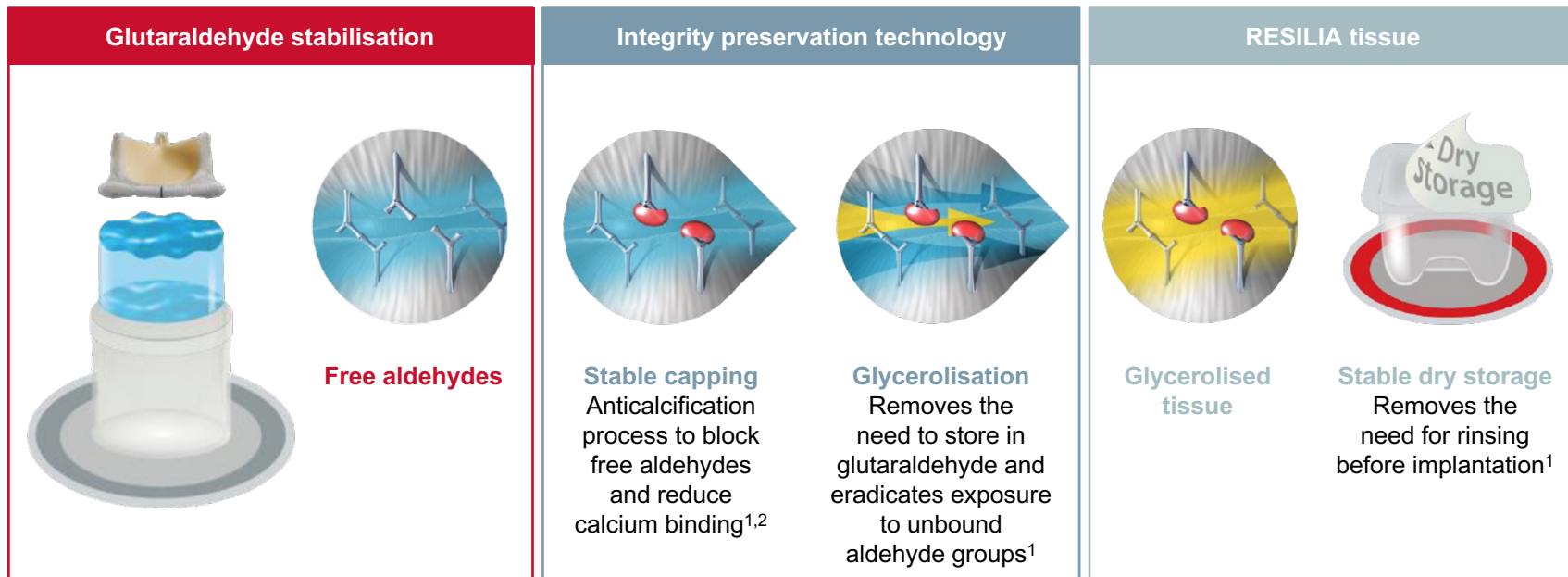
## Design characteristics

- Low profile for patients with a small aortic root
- Flexible, cobalt–chromium alloy wireform
  - Corrosion resistant
  - Good spring efficiency and fatigue resistance
  - Covered with a polyester fabric
- Scalloped silicone sewing ring
  - Conforms to the natural aortic annulus and fits against an irregular or calcified tissue bed
  - Has three equally spaced suture markers to help valve orientation and suture placement
- Integrated valve holder facilitates valve handling and suturing during implantations, and is detached by the surgeon



## RESILIA tissue mitigates residual aldehydes, a key factor in calcification

- Bovine pericardium treated with Edwards Integrity Preservation technology<sup>1</sup>
- Reduced tissue calcification enables the valve to be resilient<sup>2</sup>



**Book a meeting with an Edwards representative  
to find out more...**

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# Abbreviations

ACC: American College of Cardiology

AF: atrial fibrillation

AHA: American Heart Association

AI: aortic insufficiency

AMI: acute myocardial infarction

AR: aortic regurgitation

AS: aortic stenosis

AV: aortic valve

AVR: aortic valve replacement

BAV: bicuspid aortic valve

BSA: body surface area

CABG: coronary artery bypass graft

CAD: coronary artery disease

CE: European Conformity

CEC: clinical events committee

CI: confidence interval

CKD: chronic kidney disease

CPB: cardiopulmonary bypass

CT: computed tomography

CV: cardiovascular

CVA: cerebral vascular accident

DVI: Doppler velocity index

DVR: double valve replacement

EACTS: European Association for Cardio-Thoracic Surgery

EOA: effective orifice area

ESC: European Society of Cardiology

EuroSCORE: European System

for Cardiac Operative Risk Evaluation

FDA: US Food and Drug Administration

HTN: hypertension

ICU: intensive care unit

IDE: Investigational Device Exemption

iEOA: effective orifice area indexed to body surface area

IFU: instruction for use

IQR: interquartile range

ISO: International Organization for Standardization

KCCQ: Kansas City Cardiomyopathy Questionnaire

LBBB: left bundle branch block

LV: left ventricular

LVEDD: left ventricular end-diastolic diameter

LVEDV: left ventricular end-diastolic volume

LVESD: left ventricular end-systolic dimension

LVEF: left ventricular ejection fraction

LVOT: left ventricular obstruction tract

MDCT: multidetector computed tomography

MI: myocardial infarction

MAVR: minimally invasive aortic valve replacement

MPG: mean pressure gradient

MR: mitral regurgitation

MS: metabolic syndrome

N/A: not applicable

NYHA: New York Heart Association

PG: pressure gradient

PM: pacemaker

PPI: permanent pacemaker implantation

PPM: patient-prosthesis mismatch

PS: propensity-score

PVL: paravalvular leak

QoL: quality of life

RAMT: right anterior mini-thoracotomy

RALT: right antero-lateral mini-thoracotomy

SAV: surgical aortic valve

SAVR: surgical aortic valve replacement

SD: standard deviation

SF-12: Short Form 12

SICCH: Società Italiana di Chirurgia Cardiaca

STS: Society of Thoracic Surgeons

SVD: structural valve deterioration

TAV: tricuspid aortic valve

TAVR: transcatheter aortic valve replacement

TIA: transient ischaemic attack

TTE: transthoracic echocardiogram

VARC-2: Valve Academic Research Consortium-2

ViV: valve-in-valve

$V_{\max}$ : maximum velocity

No clinical data are available that evaluate the long term impact of RESILIA tissue in patients. Refer to device instructions for use for important warnings related to VFit technology. These features have not been observed in clinical studies to establish the safety and effectiveness of the model 11500A for use in valve-in-valve procedures. VFit technology is available on sizes 19–25 mm.

**Important safety information:**

Use of the EDWARDS INTUITY Elite valve system may be associated with new or worsened conduction disturbances, which may require a permanent cardiac pacemaker implant (PPI). The rate of PPI for the EDWARDS INTUITY Elite valve is within the range reported in the literature for various rapid deployment valves, but higher than that reported for surgical aortic valves. Physicians should assess the benefits and risks of the EDWARDS INTUITY Elite valve prior to implantation. See instructions for use for additional information.

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult [eifu.edwards.com](http://eifu.edwards.com) where applicable).

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