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

Aortic valve replacement in aortic stenosis

Surgical AVR is a fundamental intervention for severe aortic stenosis

- Improves symptoms and long-term survival[1]
- Shows good functional improvement and survival, even in elderly patients with comorbidities[2,3]

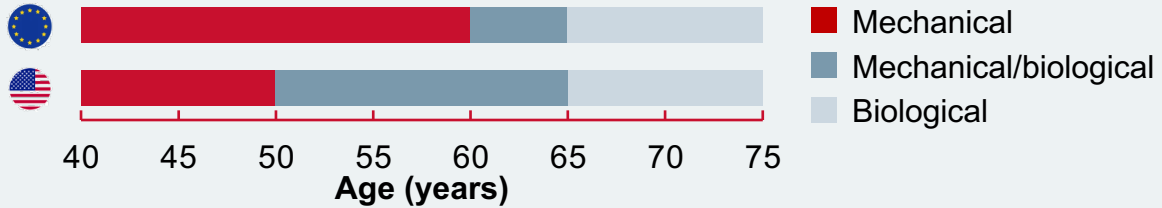
Two options for replacement aortic valves are available[4]

- **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

1. Foroutan F *et al. BMJ.* 2016; 2. Makkar RR *et al. N Engl J Med.* 2020; 3. Sharabiani MTA *et al. Open Heart.* 2016; 4. Head SJ *et al. Eur Heart J.* 2017

Guideline recommendations for the treatment of valvular heart disease

Age recommendations based on the 2020 ACC/AHA and 2021 ESC/EACTS guidelines[1,2]



2020 ACC/AHA and 2021 ESC/EACTS guidelines[1,2]

- **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[1]

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

2021 ESC/EACTS guidelines[2]

- **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

1. Otto CM *et al. J Am Coll Cardiol.* 2021; 2. Vahanian A *et al. Eur Heart J.* 2022

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

Carpentier-Edwards PERIMOUNT valve[1]
Model 2800TFX

Bioengineered
Flexible cobalt–chromium alloy stent
Pericardial leaflets
ThermaFix† treated

Carpentier-Edwards PERIMOUNT Magna valve[2]
Model 3000*

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

Carpentier-Edwards PERIMOUNT Magna Ease valve[2]
Model 3300TFX

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

INSPIRIS RESILIA aortic valve[3]
Model 11500A

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

*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.*[1]
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.*[2,3]
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.*[4]
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

1. Bourguignon T *et al. Ann Thorac Surg.* 2015; 2. Forcillo J *et al. Ann Thorac Surg.* 2013; 3. Forcillo J *et al. Ann Thorac Surg.* 2014; 4. Johnston DR *et al. Ann Thorac Surg.* 2015

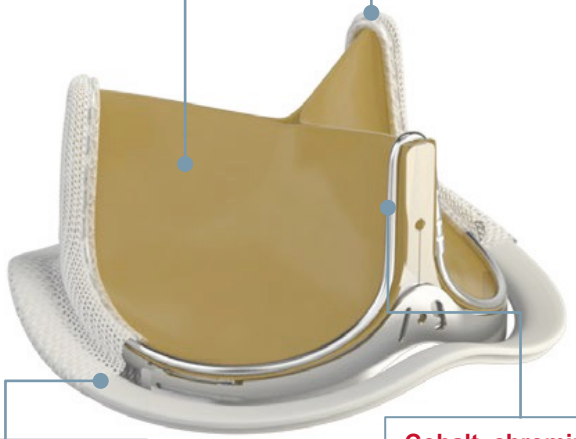
PERIMOUNT Magna and Magna Ease valves' mid-term outcomes have been assessed in almost 6,000 patients

Durability | Safety | Comparative study

Anselmi *et al.*[1] 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.*[2] 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.*[3] 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.*[4] 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.*[5] 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

1. Anselmi A *et al. Thorac Cardiovasc Surg.* 2019; 2. Theologou T *et al. J Card Surg* 2019; 3. Lam KY *et al. Ann Thorac Surg.* 2020; 4. Biancari F *et al. Ann Thorac Surg.* 2020; 5. Piperata A *et al. Eur J Cardiothorac Surg.* 2021

INSPIRIS RESILIA aortic valve (model 11500A)



Design characteristics

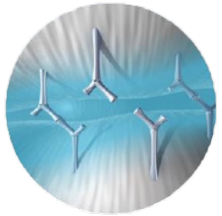
- Low profile for patients with a small aortic root
- Flexible, cobalt–chromium alloy wireform
  - Corrosion resistant
  - Good spring efficiency and fatigue resistance
  - Covered with a polyester fabric
- Scalloped silicone sewing ring
  - Conforms to the natural aortic annulus and fits against an 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

1. Edwards Lifesciences INSPIRIS RESILIA aortic valve. Model 11500a. Instructions for Use. 2020

RESILIA tissue mitigates residual aldehydes, a key factor in calcification

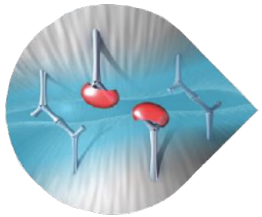
- Bovine pericardium treated with Edwards Integrity Preservation technology[1]
- Reduced tissue calcification enables the valve to be resilient[2]

Glutaraldehyde stabilisation

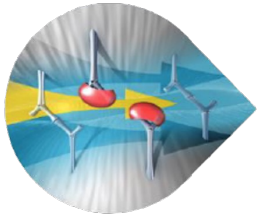


Free aldehydes

Integrity preservation technology

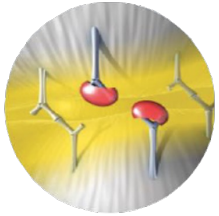


Stable capping
Anticalcification process to block free aldehydes and reduce calcium binding[1,2]



Glycerolisation
Removes the need to store in glutaraldehyde and eradicates exposure to unbound aldehyde groups[1]

RESILIA tissue



Glycerolised tissue

Stable dry storage
Removes the need for rinsing before implantation[1]

1. Edwards Lifesciences INSPIRIS RESILIA aortic valve. Model 11500a. Instructions for Use. 2020; 2. Tod TJ, Dove JS. *J Mater Sci.* 2016

Book a meeting with an Edwards representative to find out more…

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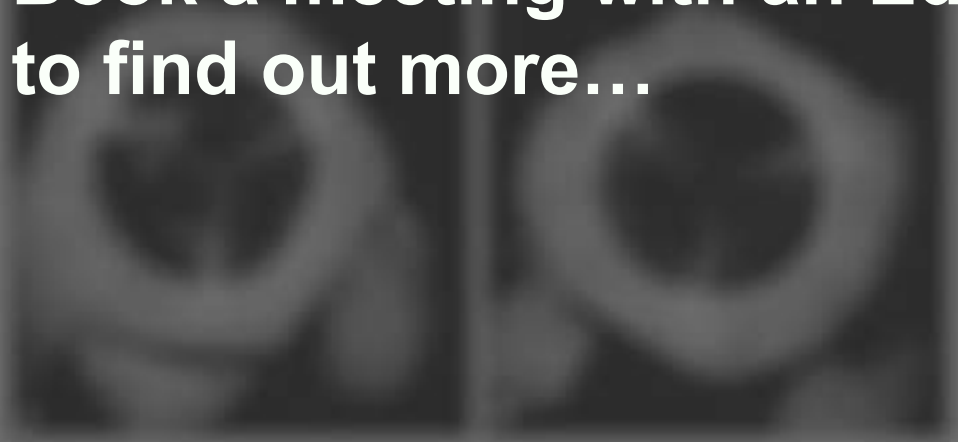

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Abbreviations

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
MIAVR: 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 where applicable).

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