CARPENTIER-EDWARDS PERIMOUNT

MAGNA EASE

PERICARDIAL AORTIC BIOPROSTHESIS

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Introduction

- Built of the Magna valve platform with proven **unsurpassed hemodynamics**
- Designed for **long-term endurance**
- Includes leaflets treated with the **ThermaFix process**
- Incorporates design features that make it **easy to implant**

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Low Profile

- Eased insertion through small incisions or in small aortic roots
- Ample clearance of the sinotubular junction and potentially easier aortotomy closure
- Allows for better overall access and maneuverability in the operative field

Magna Ease valve

Magna valve

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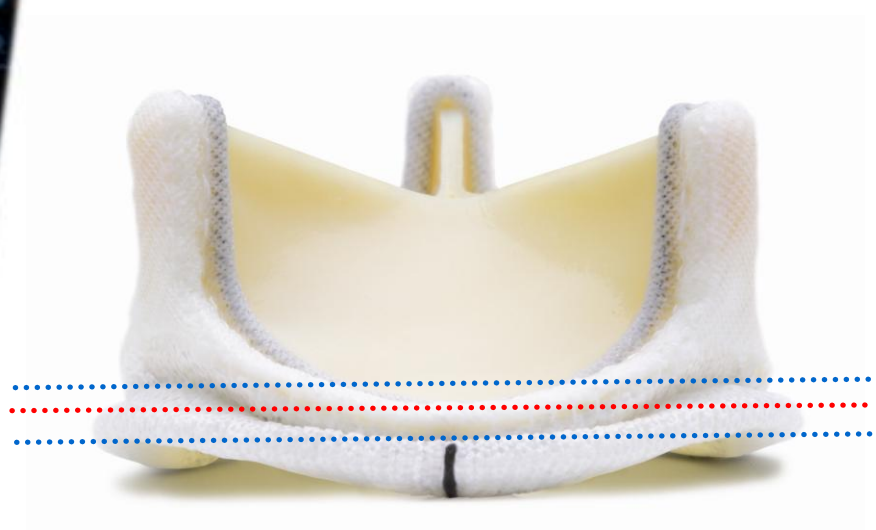
Low Stent Base

- Maximized clearance of the coronary ostia, particularly in patients with irregular or challenging anatomy



Magna Ease valve

Magna valve

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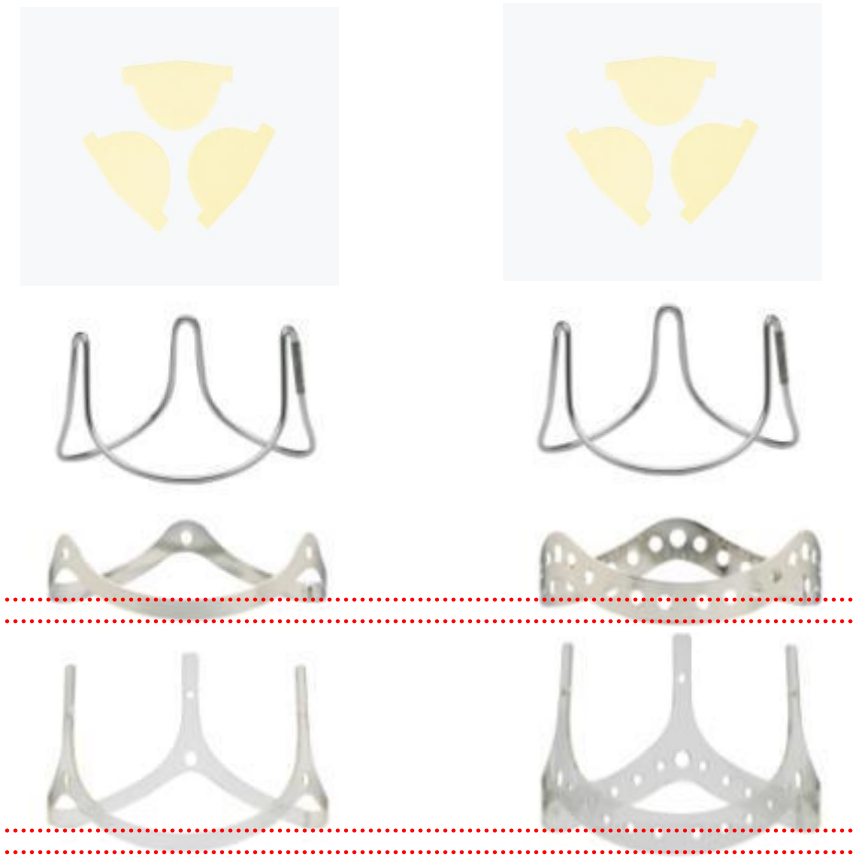
Magna Ease Design

- Built on the proven PERIMOUNT platform
- Elgiloy and polyester bands have been reduced by ~1.5 mm
  - Elgiloy band has been increased in thickness to match the strength of Magna



Magna Ease valve

Magna valve

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Ease of Implantation

Sleek commissure posts

Low profile

Low stent base

Scalloped and compliant sewing ring

Suture markers

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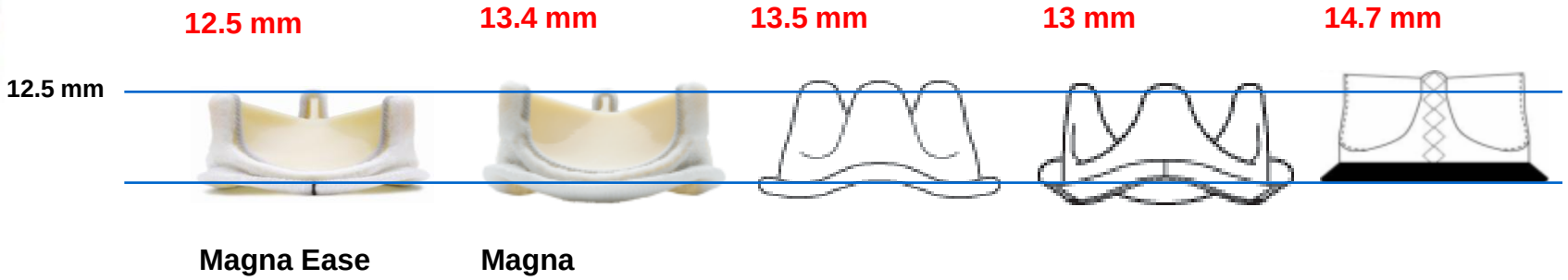
Lower profile- comparisons



Size = 23 mm

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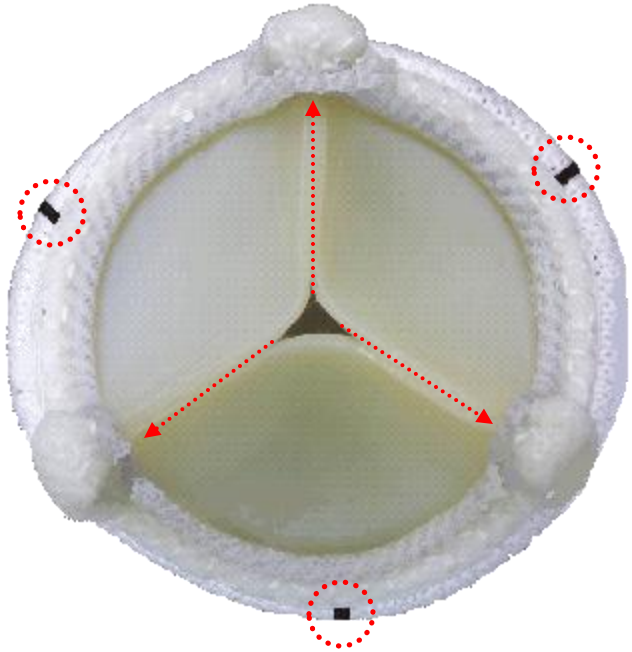
Suture Markers



- Three mid-commissure markers aid in valve orientation and suture placement

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Hemodynamics

- The Magna Ease valve is built on the Magna valve platform with proven unsurpassed hemodynamics
  - Industry-leading EOAs and low gradients documented in multiple published studies
  - Hemodynamic performance proven to be better than some stentless valves
  - Hemodynamic stability up to 17 years post-implantation

Carpentier-Edwards
PERIMOUNT Pericardial
Bioprosthesis 21 mm

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The Carpentier-Edwards Perimount Magna aortic xenograft: a new design with an improved hemodynamic performance☆

María José Dalmau[a,*], José María González-Santos[a], Javier López-Rodríguez[a], Maria Bueno[a], Antonio Arribas[b]

Echocardiographic results at 11 months postoperatively

	19	21	23	25
Mean Pressure Gradient (mmHg)				
Magna	11.9 ± 4.1	9.8 ± 3.3	9.1 ± 3.3	8.4 ± 2.6
PERIMOUNT	16.0 ± 4.8	13.4 ± 5.7	12.5 ± 3.5	10.7 ± 6.6
Effective Orifice Area (cm^2)				
Magna	1.58 ± 0.29	1.90 ± 0.46	2.07 ± 0.33	2.33 ± 0.18
PERIMOUNT	1.28 ± 0.13	1.69 ± 0.41	1.87 ± 0.28	1.89 ± 0.59
Patient-Prosthesis Mismatch				
Magna	1 (20%)	2 (16%)	1 (6.6%)	0%
PERIMOUNT	7 (77%)	4 (22%)	1 (10%)	0%

- **Key Points:**
  - Magna demonstrated ***significantly*** lower peak and mean gradients compared to PERIMOUNT
  - The EOAs for all sizes was significantly larger in the Magna group

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EOAI Comparison

PERIMOUNT Magna valve

BSA (m²)	EOAI by Valve Size			
Valve Size (mm)	19	21	23	25
EOA[1] (cm²)	1.58	1.90	2.07	2.33
1.0	1.58	1.90	2.07	2.33
1.1	1.44	1.73	1.88	2.12
1.2	1.32	1.58	1.73	1.94
1.3	1.22	1.46	1.59	1.79
1.4	1.13	1.36	1.48	1.66
1.5	1.05	1.27	1.38	1.55
1.6	0.99	1.19	1.29	1.46
1.7	0.93	1.12	1.22	1.37
1.8	0.88	1.06	1.15	1.29
1.9	0.83	1.00	1.09	1.23
2.0	0.79	0.95	1.04	1.17
2.1	0.75	0.90	0.99	1.11
2.2	0.72	0.86	0.94	1.06
2.3	0.69	0.83	0.90	1.01
2.4	0.66	0.79	0.86	0.97
2.5	0.63	0.76	0.83	0.93

EOAI* > 0.85 recommended.[2,3]

EOAI* > 0.75 recommended.[4]

EOAI* ≤ 0.75 is not recommended.[4]

**Effective Orifice Area Index (EOAI) = EOA/BSA Ratio (cm²/m²)*

PERIMOUNT valve

BSA (m²)	EOAI by Valve Size			
Valve Size (mm)	19	21	23	25
EOA[1] (cm²)	1.28	1.69	1.87	1.89
1.0	1.28	1.69	1.87	1.89
1.1	1.16	1.54	1.70	1.72
1.2	1.07	1.41	1.56	1.58
1.3	0.98	1.30	1.44	1.45
1.4	0.91	1.21	1.34	1.35
1.5	0.85	1.13	1.25	1.26
1.6	0.80	1.06	1.17	1.18
1.7	0.75	0.99	1.10	1.11
1.8	0.71	0.94	1.04	1.05
1.9	0.67	0.89	0.98	0.99
2.0	0.64	0.85	0.94	0.95
2.1	0.61	0.80	0.89	0.90
2.2	0.58	0.77	0.85	0.86
2.3	0.56	0.73	0.81	0.82
2.4	0.53	0.70	0.78	0.79
2.5	0.51	0.68	0.75	0.76

EOAI* > 0.85 recommended.[2,3]

EOAI* > 0.75 recommended.[4]

EOAI* ≤ 0.75 is not recommended.[4]

**Effective Orifice Area Index (EOAI) = EOA/BSA Ratio (cm²/m²)*

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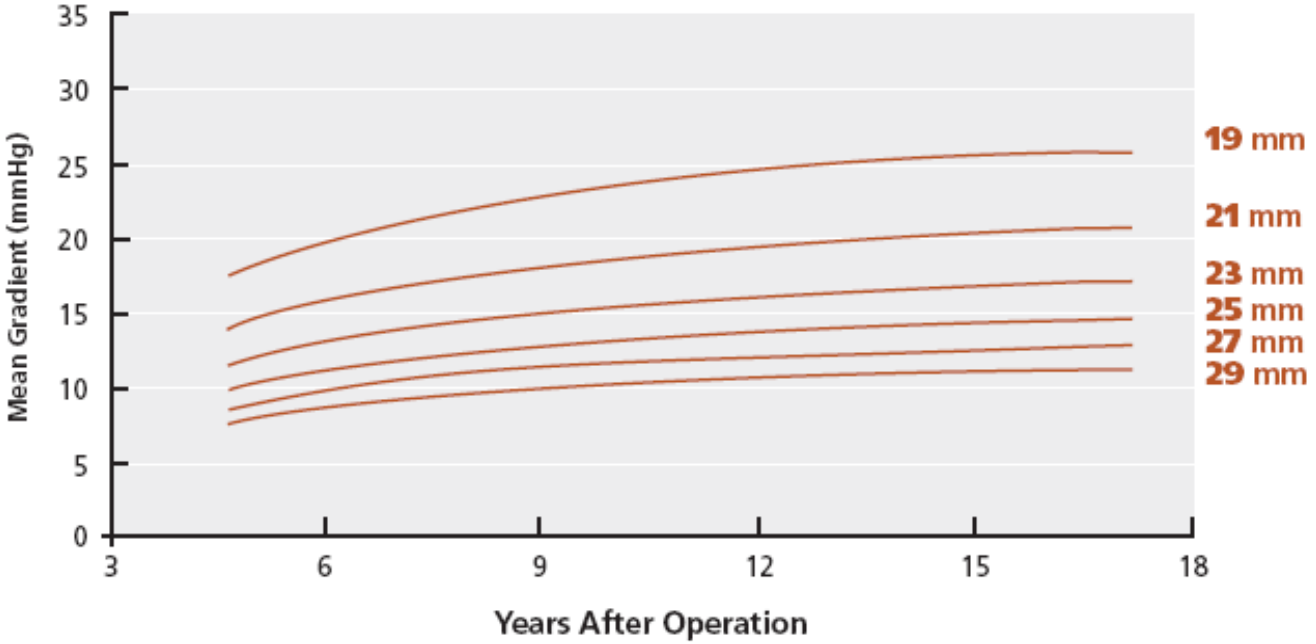
Hemodynamic Stability During 17 Years of the Carpentier-Edwards Aortic Pericardial Bioprosthesis

Michael K. Banbury, MD, Delos M. Cosgrove III, MD, James D. Thomas, MD, Eugene H. Blackstone, MD, Jeevanantham Rajeswaran, MS, J. Edward Okies, MD, and Robert M. Frater, MD

Evolution of Mean Gradient Over Time[1]



The Carpentier-Edwards aortic pericardial bioprosthesis can be anticipated to have an acceptable long-term transvalvular gradient and effective orifice size that will change trivially up to 17 years after implantation.

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Durability

- The Magna Ease valve is designed for long-term endurance
  - Stress points minimized by utilizing optimally-matched leaflets mounted under the stent
  - High leaflet stability achieved through streamlined internal framework
  - Built on PERIMOUNT valve platform with durability up to 20 years

Durability

Mean Age	# of Pts.	Endpoint	Mean Follow-up	Pt. Follow-up Years
72.6	1133	18 yrs.	5.5 yrs.	6180

Actuarial Freedom from SVD				
All Ages	> 70	60-70	> 60	< 60
68 ± 12%	99 ± 1%	77±12%	85 ± 8%	45 ± 15%

Actuarial Freedom from Valve Related Death	Actuarial Freedom from Thromboebolism	Actuarial Freedom from Valve Related Complications
95 ± 2%	92.2 ± 2%	47 ± 8%

Michel R. Aupart, Alain Mirza, Yvon A. Meurisse, Agnes L. Sirinelli, Paul H. Neville, Michel A. Marchard

The Journal of Heart Valve Disease 2006; 15(6):768-776

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Conclusion

“Magna Ease, to try it is to adopt it!”

More than 10’000 implanted in Europe

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Edwards

Helping Patients is Our Life's Work, and *life is now*

E1191/04-09/HVT