



30 November 2022 s.d. 20 November 2026  
Jl. Jaksa Agung Suprpto No.2 MALANG 65111  
Telp. ( 0341 ) 362101, Fax. ( 0341 ) 369384  
E-mail : [staf-rsu-drsaifulanwar@jatimprov.go.id](mailto:staf-rsu-drsaifulanwar@jatimprov.go.id)  
Website : [www.rsusaifulanwar.jatimprov.go.id](http://www.rsusaifulanwar.jatimprov.go.id)

RSSA

## NOTA DINAS

Kepada	:	Ka.Bidang Pelayanan Medik	Diterima tanggal	:	15-5-2024
Dari	:	Instalasi Bedah Sentral	Nomor Agenda	:	766
Tanggal	:	15 Mei 2024	Diteruskan Kepada	:	
Nomor	:	027/ 98 / 2.6 /102.7/2024	1.		
Lampiran	:	-	2.		
Perihal	:	Belanja Bahan Habis Pakai	3.		
Tindakan	:		4.		

Bersama ini kami mengajukan permintaan pengajuan, dengan rincian sebagai berikut :

No	Nama Barang	Spesifikasi	Jml	Satuan	Ket
1	Carpentier-Edwards@ Premount magna Mitral Ease Pericardial Bioprosthesis	3300TFX	1	box	
		3300TFX19MM	1	box	
		3300TFX21MM	1	box	
		3300TFX23MM	1	box	
		3300TFX25MM	1	box	
		3300TFX27MM	1	box	
		3300TFX29MM	1	box	

Demikian atas perhatiannya kami sampaikan terima kasih.

*Ma de C P*  
*me-tu*

Hormat Kami  
Ka.Instalasi Bedah Sentral

dr. Krisna Yuarno Phatama, Sp.OT (K)  
NIP. 19811130 201412 1 001

\* Disposisi Tanmed melalui e-letter

Dari : Bidang Kepada: PPTK	Paraf/ Tanda tangan Kabag/Kabid	Kegiatan	:	
		Sub Kegiatan	:	
		Sub-Sub Kegiatan	:	Pelayanan Farmasi
		Kode Rekening	:	51029999999922a
		Uraian Kode Rekening	:	Bjg-Alat/Bahan utk kegiatan kantor - Perlengkapan Dmas (Alkes Pakai Hbs).
		Pagu Anggaran	:	105.100.000.000,-
		Realisasi	:	
		Sisa Anggaran	:	
Dari : PPTK Kepada: Ka. IPBJ				Paraf/ Ttd PPTK

Lembar Rekomendasi:

Dari Ka. IPBJ Kepada : PPTK	Paraf/ Ttd Ka. Instalasi
Dari PPTK Kepada :	Paraf/ Ttd PPTK



KSM BEDAH  
RSUD dr. SAIFUL ANWAR  
PROVINSI JAWA TIMUR

NOTA – DINAS

Kepada Yth : Ka.Instalasi Bedah Sentral RSUD.dr.Saiful Anwar  
Surat Dari : Ketua KSM Bedah RSUD.dr.Saiful Anwar  
Nomor : 442 / 084 / 3.2/102.7/2024  
Tanggal : 14 Mei 2024  
Sifat : Cito  
Lampiran : -  
Perihal : Permohonan Pengadaan alat

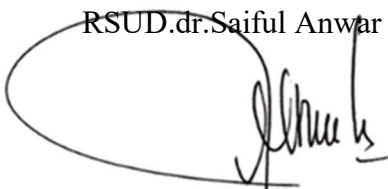
Sehubungan dengan surat dari Ka.Divisi Bedah Toraks Kardiak dan Vaskular tanggal 14 Mei 2024 nomor: 177/HBTKVI/SP/V/2024 perihal pada pokok surat dan dalam rangka kelancaran pelayanan Divisi Bedah Toraks Kardiak dan Vaskular, maka bersama ini kami mengajukan permohonan pengadaan alat sebagai berikut:

No	Nama Barang	Keterangan
1	Carpentier-Edwards@ Premount magna Mitral Ease Pericardial Bioprosthesis	List Barang Terlampir
2	Carpentier-Edwards@ Premount magna Mitral Ease Pericardial Bioprosthesis	

(Surat dari Kepala Divisi Bedah TKV terlampir).

Demikian atas perhatian dan kerjasamanya kami sampaikan terima kasih.

Ketua KSM Bedah  
RSUD.dr.Saiful Anwar



**dr. Artono Isharanto, Sp. B, Sp. BTKV Subsp. T. (K)**  
**NIP. 19680102 199803 1 013**



**KEMENTERIAN KESEHATAN REPUBLIK INDONESIA  
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN**

Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950

Telepon : (021) 5201590 Pesawat 2029, 8011

Faksimile : (021) 52964838 Kotak Pos : 203



Berdasarkan Peraturan Menteri Kesehatan R.I Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

**NOMOR IZIN EDAR**

**ALAT KESEHATAN**

**KEMENKES RI AKL 30503811368**

Nama Dagang / Merek : **CARPENTIER-EDWARDS® PERIMOUNT Magna® Mitral Ease™**  
**Pericardial Bioprosthesis**

Kelompok / Kelas Resiko : Non Elektromedik Steril / D

Kategori Produk : Peralatan Kardiologi

Sub Kategori : Peralatan Kardiologi Prostetik

Jenis Produk : Replacement heart valve.

Tipe / Ukuran : Terlampir

Kemasan : Dus

Nama Produsen / Pabrikan : EDWARDS LIFESCIENCES (SINGAPORE) PTE., LTD., Singapore  
Untuk EDWARDS LIFESCIENCES LLC., United States  
Melalui EDWARDS LIFESCIENCES (THAILAND) LIMITED, Thailand

Nama Pendaftar : PT. REKAMILENIUMINDO SELARAS, DKI Jakarta

Atas dasar lisensi dari : -

**Ketentuan**

1. Persetujuan izin edar berlaku sampai dengan 15 September 2023.
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Izin edar ini merupakan persetujuan perpanjangan dari Nomor Izin Edar Alat Kesehatan KEMENKES RI AKL 30503811368 tanggal 27 Agustus 2020. Dengan demikian izin edar sebelumnya dinyatakan tidak berlaku.
4. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
5. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
6. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.

**Jakarta, 30 Juli 2021**

	Ditandatangani Secara Elektronik Oleh :
	a.n Direktur Jenderal
	Direktur Penilaian Alat Kesehatan dan PKRT
	Ir. Sodikin Sadek, M.Kes NIP.19621203 198603 1 004



**Catatan:**

- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1

Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.

- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSR.E.



KEMENTERIAN KESEHATAN REPUBLIK INDONESIA  
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN

Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950  
Telepon : (021) 5201590 Pesawat 2029, 8011  
Faksimile : (021) 52964838 Kotak Pos : 203



LAMPIRAN

NOMOR IZIN EDAR  
ALAT KESEHATAN  
KEMENKES RI AKL 30503811368

No.	Deskripsi	Tipe / Kode
1	Carpentier-Edwards	7300TFX25
2	Carpentier-Edwards	7300TFX27
3	Carpentier-Edwards	7300TFX29
4	Carpentier-Edwards	7300TFX31
5	Carpentier-Edwards	7300TFX33

Dengan ketentuan bahwa izin edar tersebut hanya berlaku untuk deskripsi dan tipe / kode produk yang tercantum dalam lampiran ini

Jakarta, 30 Juli 2021



Ditandatangani Secara Elektronik Oleh :  
a.n Direktur Jenderal  
Direktur Penilaian Alat Kesehatan dan PKRT  
Ir. Sodikin Sadek, M.Kes  
NIP.19621203 198603 1 004



Catatan:  
- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1  
Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.  
- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSR.E.



inner jar label

**Carpentier-Edwards PERIMOUNT  
Magna Mitral Ease**



**EN** Caution

Product cannot be returned if carbon seal is broken n.

04 12



**Edwards Lifesciences LLC**  
One Edwards Way  
Irvine, CA 92614 USA

**Edwards Lifesciences GmbH**  
Edisonstraße 6  
85376 Unterschleißheim, Germany

**EC REP**

**Edwards Lifesciences LLC**  
One Edwards Way  
Irvine, CA 92614 USA  
Made in OMAN BY GANAREPUBLIC

**EC REP**  
Edwards, Watson & Jones Services GmbH  
Eckendorfer 6  
85716 Unterschleißheim, Germany  
Made in **GERMANY**

Edwards, Watson & Jones LLC  
One Edwards Way  
Irvine, CA 92614 USA  
Made in **USA**

**E** Edwards Lifesciences



**ThermaFix™ Process**

**Magn**

7300TFX  
RIMOUNT  
Mitral Ease  
25 mm  
Mitral

1234567890112

REF 7300TFX25MM

Qty.  :1

Edwards Lifesciences

**EN** Carpentier-Edwards PERIMOUNT  
Magna Mitral Ease  
Pericardial Bioprosthesis

Chemically sterilized

**Caution:** Do not freeze. Store between 10 °C and 25 °C. Packed in glutaraldehyde - avoid contact with skin and eyes. Contents sterile and nonpyrogenic if jar is unopened or undamaged.

SN 77777777

25 mm

2030-12-3

2023-12-09

Mitral

BARCODE FPO

BARCODE FPO

30

0.7(11)210

BARCODE FPO

DOC-0114504 A

Di Import dan di Distribusikan Oleh :  
PT.REKAMILENIUMINDO SELARAS  
JAKARTA – INDONESIA

Nama Produk : CARPENTIER-EDWARDS® PERIMOUNT  
Magna® Mitral Ease™ Pericardial Bioprosthesis  
Nama Pabrik : EDWARDS LIFESCIENCES (SINGAPORE) PTE., LTD Singapore  
untuk EDWARDS LIFESCIENCES LLC. (Irvine) United States melalui  
EDWARDS LIFESCIENCES (THAILAND) LTD.Thailand  
KEMENKES RI AKL

[illegible]

inner jar's lid label

7300TFX  
PERIMOUNT™  
Magna Mitral Ease™

SN 77777777

2030-12-31  
(YYY-MM-DD)

TheraFix™ Process

Mitral

25 mm

DATA MATRIX  
BARCODE FPO

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# The Proven Choice

Carpentier-Edwards PERIMOUNT

## Magna Ease

Pericardial Aortic Bioprosthesis



Edwards

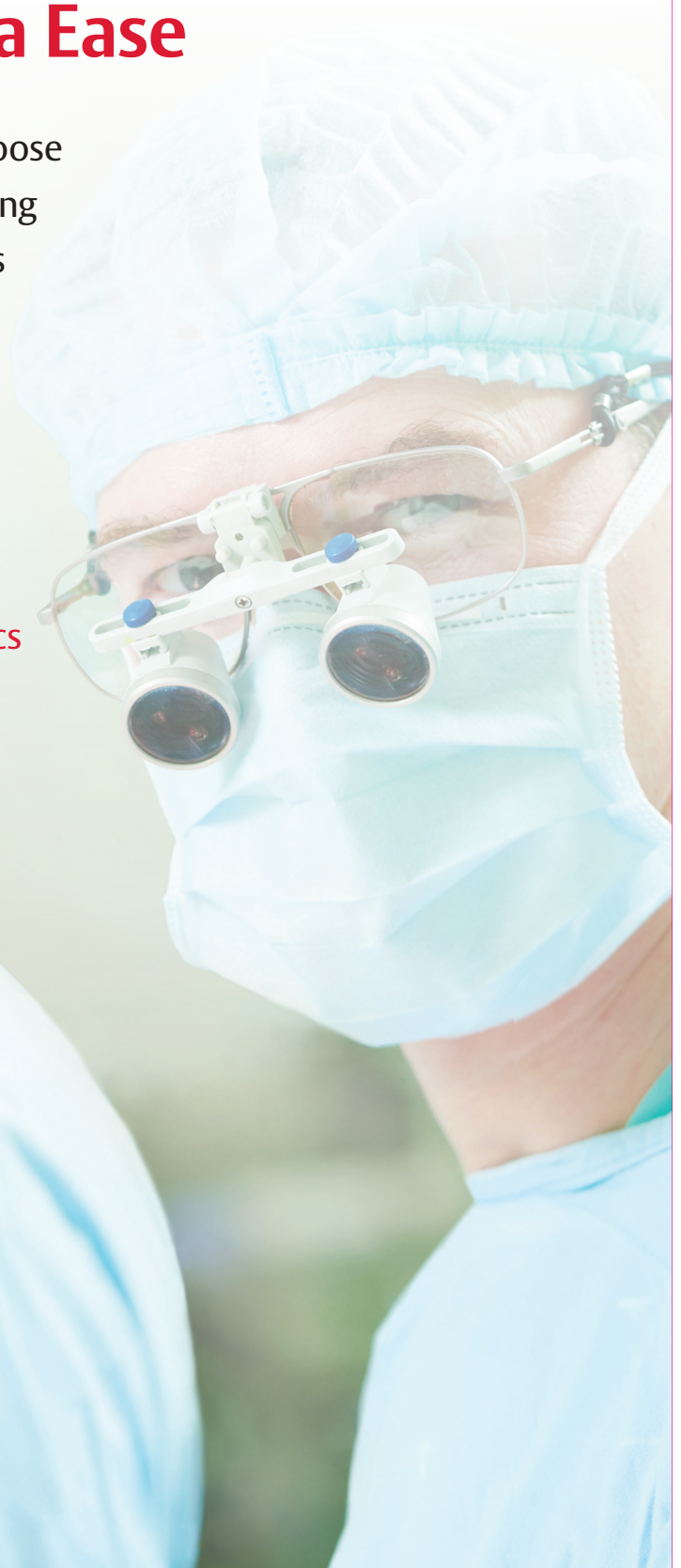
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# Carpentier-Edwards PERIMOUNT Magna Ease

With the Magna Ease valve, you can choose with confidence, knowing you are getting an industry-leading valve from Edwards Lifesciences, the leader in heart valve therapy.

Built upon the unique and proven PERIMOUNT design, the Magna Ease valve gives you and your patients:

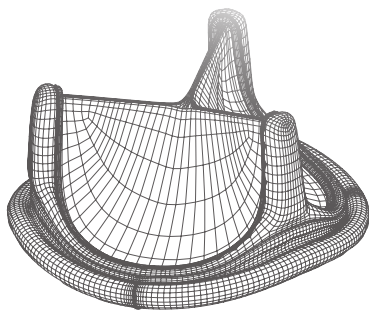
- Excellent and stable **hemodynamics**
- Excellent long-term **durability**
- A low profile, supra-annular valve that is **easy to implant**



It all starts with the

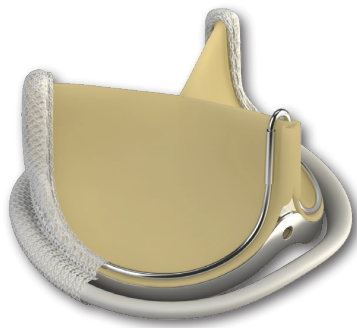
## Proven PERIMOUNT Design

The Magna Ease valve is built upon the proven, time-tested PERIMOUNT valve design, with unique design elements including:



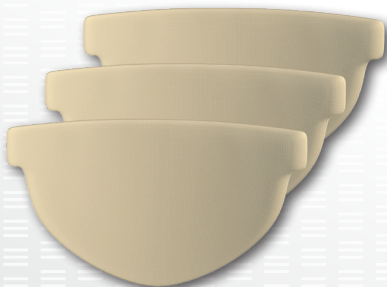
### Mathematically modeled, bioengineered design

Optimized for **hemodynamics**, **durability** and **implantability**



### Flexible cobalt-chromium alloy stent

Absorbs energy to reduce leaflet stress



### Three independent bovine pericardial leaflets

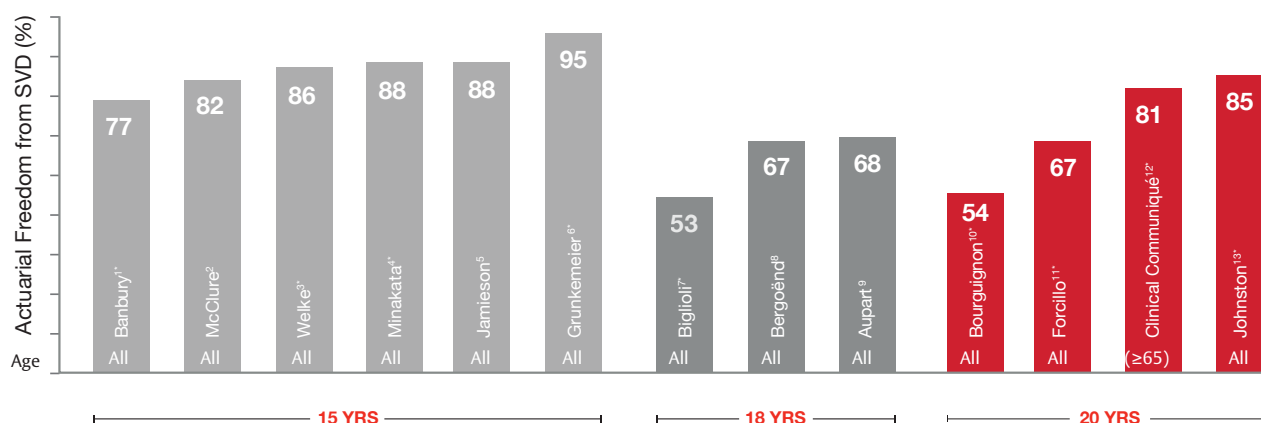
Matched for thickness and elasticity to optimize stress distribution



# Excellent Long-Term Durability

More long-term clinical study publications than any other bioprosthetic aortic valve

**20+**  
**Years** of clinical durability with  
the PERIMOUNT valve design



## After more than 1 billion cycles, the Magna Ease valve still performs like new.<sup>14</sup>

The Magna Ease valves demonstrated excellent durability after the equivalent of 25 years in simulated *in vitro* wear, with hydrodynamic performance similar to that of a new valve.



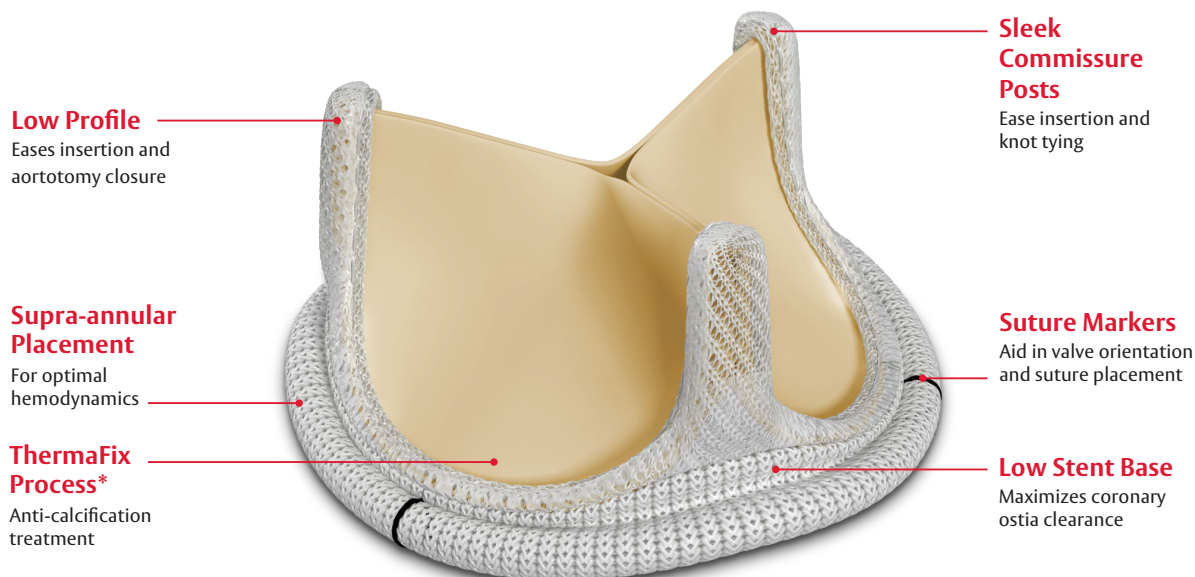
**New Valve**



**Billion Cycled Valve**

## Ease of Implant

Offers many key design features that enhance the valve's ease of implant

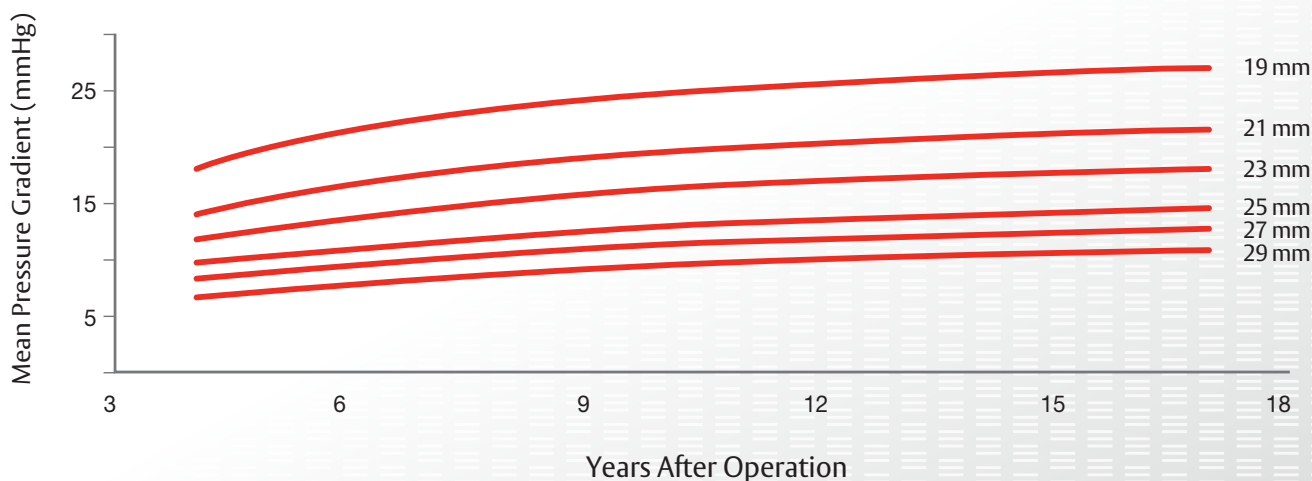


\*No clinical data are available that evaluate the long-term impact of the Carpentier-Edwards ThermaFix tissue process in patients.

## Excellent and Stable Hemodynamics

Excellent EOAs and low gradients based on the proven PERIMOUNT valve design<sup>15</sup>

**17 years**  
of hemodynamic  
stability data with the  
PERIMOUNT valve  
design



# Carpentier-Edwards PERIMOUNT valve platform

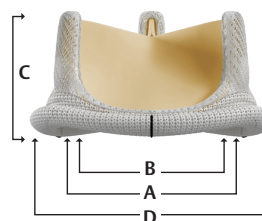
## The Surgeons' Choice

**70% of cardiac surgeons** would choose an Edwards tissue valve for themselves or a close family member.<sup>†</sup>

### Model 3300TFX Nominal Specifications (mm)

Size	19 mm	21 mm	23 mm	25 mm	27 mm	29 mm
A. Stent Diameter (TAD*)	19	21	23	25	27	29
B. Internal Diameter (Stent I.D.)	18	20	22	24	26	28
C. Profile Height	13	14	15	16	17	18
D. External Sewing Ring Diameter	24	26	28	30	32	34

\* Tissue Annulus Diameter



### Accessories

Model	Description
1133SET	Sizers – Complete Set
1133	Sizers – Individual
TRAY1133	Accessory Tray
1111	Reuseable Handle
1126	Longer Single-Use Handle

<sup>†</sup>Based on a double-blinded survey of 255 U.S. cardiac surgeons conducted in Q4 2014. Data on file.

#### Brief Summary: Aortic Bioprostheses

**Indications:** For use in patients whose aortic valvular disease warrants replacement of their natural or previously placed prosthetic valve.

**Contraindications:** Do not use if surgeon believes it would be contrary to the patient's best interests. **Complications and Side Effects:** Stenosis, regurgitation, endocarditis, hemolysis, thromboembolism, valve thrombosis, nonstructural dysfunction, structural valve deterioration, anemia, arrhythmia, hemorrhage, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, angina, any of which could lead to reoperation, explantation, permanent disability, and death. **Warnings:** Alternative therapies should be considered in the presence of conditions affecting calcium metabolism or when calcium containing chronic drug therapies are used, including children, adolescents, young adults, and patients on a high calcium diet or maintenance hemodialysis. Should be used with caution in the presence of severe systemic hypertension or when anticipated patient longevity is longer than the known longevity of the prosthesis.

**CAUTION:** Federal (United States) law restricts this device to sale by or on the order of a physician. See Instructions for Use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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## References for the Carpentier-Edwards PERIMOUNT Magna Ease Brochure

1. Banbury MK, Cosgrove DM III, White JA, et al. Age and Valve Size Effect on the Long-term Durability of the Carpentier-Edwards Aortic Pericardial Bioprosthesis. *Ann Thorac Surg.* 2001;72(3):753-757. (Cohort size = 267, mean age = 65 ± 12 yrs. Number at risk for Explant for SVD at last follow-up not reported)
2. McClure RS, Narayanasamy N, Wiegerinck 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)
3. Welke KF, Wu Y, Grunkemeier GL, Ahmad A, Starr A. Long-term results after Carpentier-Edwards pericardial aortic valve implantation, with attention to the impact of age. *The Heart Surgery Forum.* 2011;14(3):E160-165.
4. Minakata K et al. Long-Term Outcome of the Carpentier-Edwards Pericardial Valve in the Aortic Position in Japanese Patients. *Circulation Journal* 2014;78:882- 889. (Cohort size = 574, mean age = 71.9 yrs. Number at risk for Structural Deterioration at 15-year follow-up = 54)
5. Jamieson WR, Germann E, Aupart MR, et al. 15-year Comparison of Supra-annular Porcine and PERIMOUNT Aortic Bioprostheses. *Asian Cardiovasc Thorac Ann.* 2006;14(3):200-205. (Cohort size = 1,430, mean age = 69.5 ± 10.4 yrs. Number at risk for SVD at last follow-up = 33)
6. Grunkemeier GL, Furnary AP, Wu Y, Wang L, Starr A. Durability of pericardial versus porcine bioprosthetic heart valves. *The Journal of Thoracic and Cardiovascular Surgery.* 2012;144(6):1381-1386.
7. Biglioli P, Spampinato N, Cannata A, et al. Long-term outcomes of the Carpentier-Edwards pericardial valve prosthesis in the aortic position: effect of patient age. *J Heart Valve Dis.* 2004;13(1):S49-51. (Cohort size = 327, mean age = 67.2 ± 10.6 yrs. Number at risk for Prosthesis Replacement at last follow-up not reported)
8. Bergoënd E, Aupart MR, Mirza A, et al. 20 years' durability of Carpentier-Edwards Perimount stented pericardial aortic valve. In: Yankah CA, Weng Y, Hetzer R, eds. *Aortic Root Surgery The Biological Solution.* Berlin: Springer; 2010:441-451. (Cohort size = 1,857, mean age = 69.8 yrs, Number at risk for Structural Valve Deterioration at last follow-up not reported)
9. Aupart MR, Mirza A, Meurisse YA, et al. Perimount Pericardial Bioprosthesis for Aortic Calcified Stenosis: 18-year Experience with 1133 Patients. *J Heart Valve Dis.* 2006;15(6):768-775. (Cohort size = 1,133, mean age = 72.6 yrs. Number at risk for SVD at last follow-up = 2)
10. Bourguignon T, et al. Very Long-Term Outcomes of the Carpentier-Edwards PERIMOUNT Valve in Aortic Position. *Ann Thorac Surg.* 2015 Mar;99(3):831-7. (Cohort size = 2,659, mean age = 71 ± 10.4 yrs. Number at risk for explant for Structural Valve Deterioration = 28).
11. Forcillo J et al. Carpentier-Edwards Pericardial Valve in the Aortic Position: 25-Years Experience. *Ann Thorac Surg* 2013;96:486-93. (Cohort size = 2,405, mean age = 71 yrs. | Number at risk for Structural Deterioration at last follow-up = 30)
12. Clinical Communiqué. Carpentier-Edwards PERIMOUNT Aortic Pericardial Bioprosthesis 20-year Results. Data on file at Edwards Lifesciences, 2003. (Cohort size = 267, mean age = 65 ± 12 yrs. For patients ≥65, number at risk for explant due to SVD at last follow-up = 2)
13. Johnston DR, Soltész EG, Vakil N, et al. Long-term durability of bioprosthetic aortic valves: implications from 12,569 implants. *Ann Thorac Surg.* 2015 Apr;99(4):1239-47. (Cohort size = 12,569, mean age = 71 ± 11 yrs. Number at risk for explant for Structural Valve Deterioration at 20 year follow-up = 54).
14. Raghav V, et al. Long-term durability of Carpentier-Edwards Magna Ease valve: A one billion cycle in-vitro study. *Ann Thorac Surg* 2016;101:1759-67.
15. Wendt D, et al. The new St Jude Trifecta versus Carpentier-Edwards Magna and Magna Ease aortic bioprosthesis: Is there a hemodynamic superiority? *J Thorac Cardiovasc Surg.* 2014;147(5):1553-1560.

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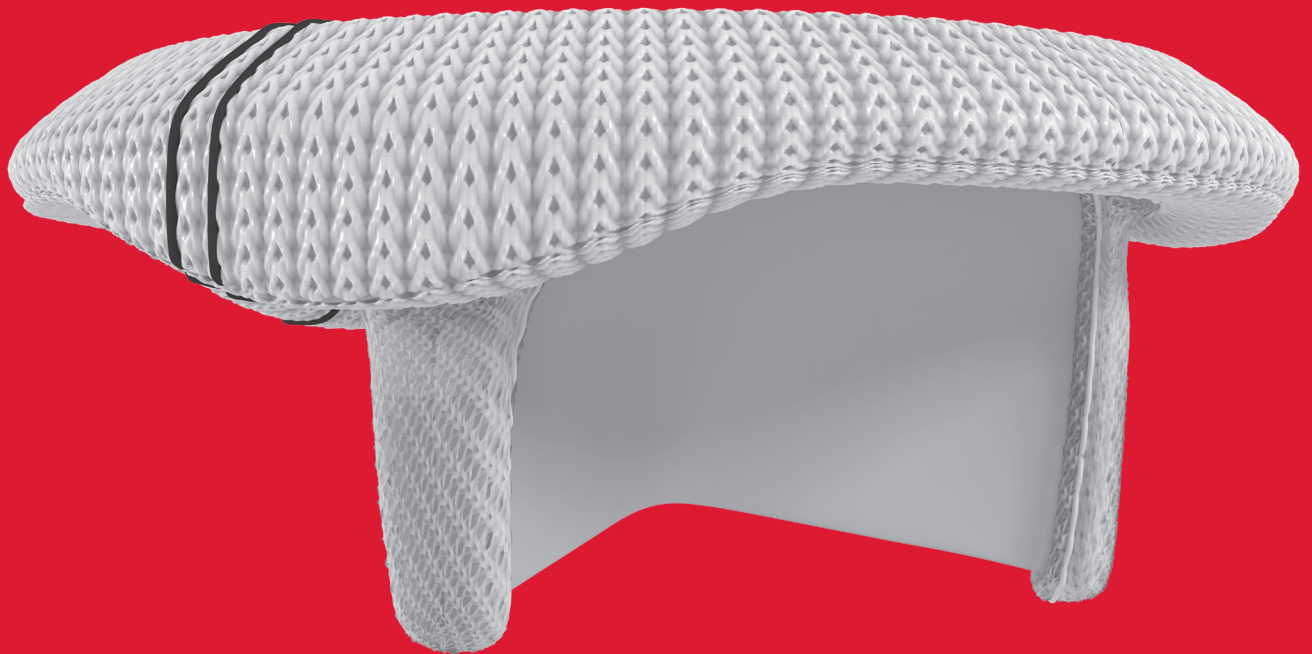
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Edwards



# Make the choice you would make for yourself



Carpentier-Edwards PERIMOUNT

**Magna Mitral Ease**

Pericardial Bioprosthesis



Edwards

Carpentier-Edwards PERIMOUNT  
**Magna Mitral Ease**  
Pericardial Bioprosthesis

With the Magna Mitral Ease valve, you can choose with confidence, knowing you are getting a valve from Edwards Lifesciences, the worldwide leader in heart valve therapy. Built upon the unique and proven PERIMOUNT valve design, the Magna Mitral Ease valve gives you and your patients:

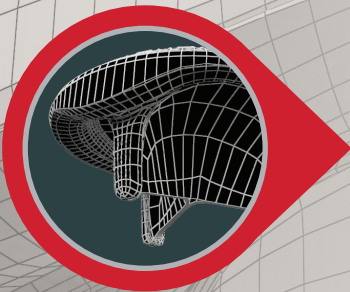
- **Ultra-low** profile, with reduced ventricular projection by up to 40%\*
- Exceptional **long-term durability**
- **Ease of implant**

\*As compared to the Carpentier-Edwards PERIMOUNT Theon mitral valve

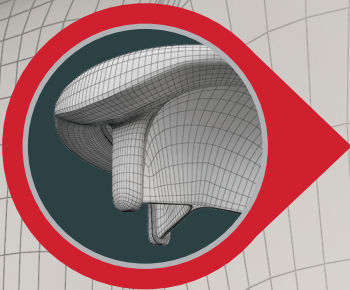
It all starts with the

# Proven PERIMOUNT design

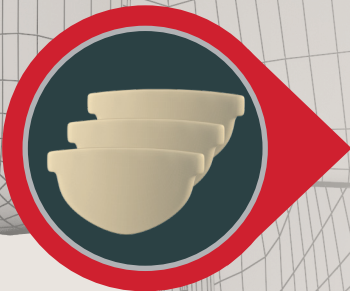
The Magna Mitral Ease valve is built upon the proven, time-tested PERIMOUNT valve design, with unique design elements including:



Mathematically modeled, bioengineered design  
Intended to optimize **implantability, hemodynamics** and  
**long-term durability**



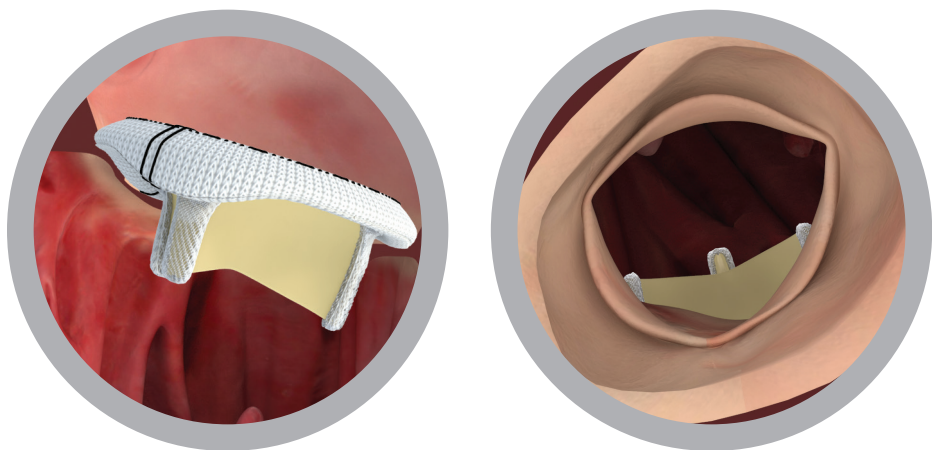
Flexible cobalt-chromium alloy stent  
Absorbs energy to reduce leaflet stress



Three independent bovine pericardial leaflets  
Matched for thickness and elasticity to optimize stress distribution

## Ultra-low profile, with reduced ventricular projection by up to 40%\*

- Supra-annular position and asymmetrical design, help to reduce ventricular projection†



\*†As compared to the Carpentier-Edwards PERIMOUNT Theon mitral valve

## Exceptional long-term durability

- Built on the proven performance of the PERIMOUNT valve design, with published clinical durability of up to 20 years

### Actuarial freedom from structural valve deterioration<sup>‡</sup> perimount mitral bioprostheses

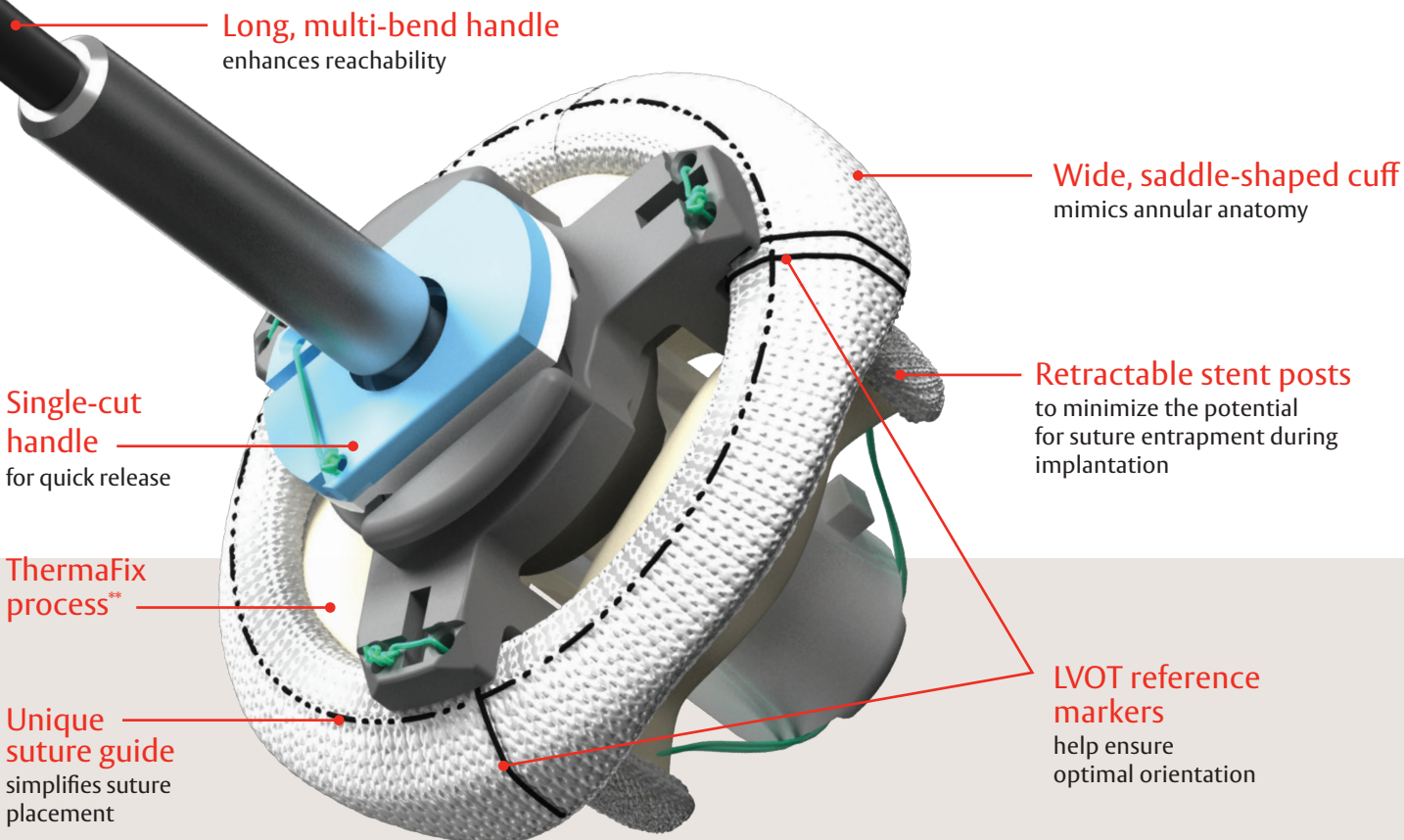


<sup>‡</sup>Patients and results are a subset of each study. Reporting methods vary among literature sources. See references for definitions.



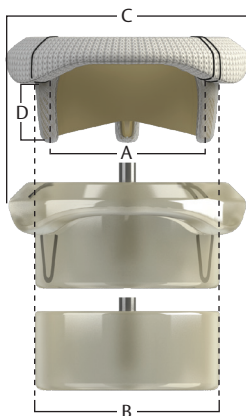
## Ease of implant

- Wide, contoured cuff with unique anterior saddle and lateral contour to mimic the shape of the native mitral anatomy

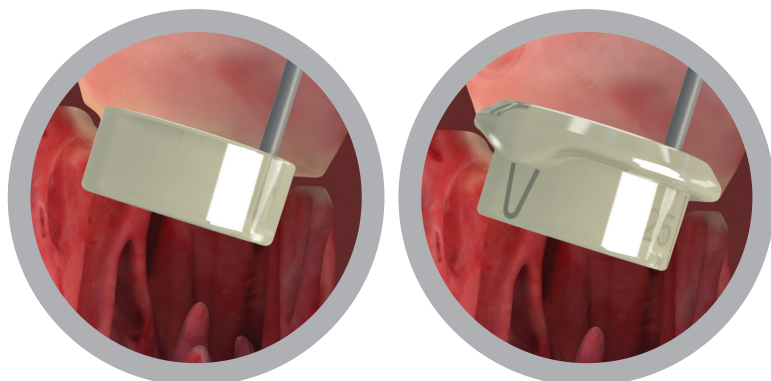


\*\*No clinical data are available that evaluate the long-term impact of the Carpentier-Edwards ThermaFix treatment in patients.





Model 7300TFX nominal specifications (mm)					
Size	25 mm	27 mm	29 mm	31 mm	33 mm
A. Stent diameter (wireform)	25	27	29	31	31
B. Tissue annulus diameter	28	29.5	31.5	33.5	33.5
C. External sewing ring diameter	36	38	40	42	44
D. Anterior effective profile	7	7.5	8	8.5	8.5



Pre-attached barrel and replica sizers facilitate valve sizing

#### Accessories

Barrel sizer accessory set	SET1173B
Replica sizer accessory set	SET1173R
Flexible, reusable handle	1173



Flexible handle with valve attached

#### References

1. Aupart, MR, et al. Carpentier-Edwards pericardial valves in the mitral position: ten-year follow-up. J Thorac Cardiovasc Surg. 1997 Mar;113(3):492-8. (Freedom from structural deterioration; n = 150; mean age = 62.9 ± 11.9 yrs)
2. Jamieson, WRE, et al. Structural Valve Deterioration in Mitral Replacement Surgery: Comparison of Carpentier-Edwards Supra-Annular Porcine and PERIMOUNT Pericardial Bioprostheses. J Thorac Cardiovasc Surg. 1999 Aug;118:297-305. (Freedom from explant due to structural valve deterioration; n = 429; mean age = 60.7 ± 11.7 yrs)
3. Murakami, T, et al. Aortic and mitral valve replacement with the Carpentier-Edwards pericardial bioprosthesis: 10-year results. J Heart Valve Dis. 1996 Jan;5(1):45-9. (Freedom from structural deterioration; n = 57, mean age = 55.1 ± 13.2 yrs)
4. Poirier, NC, et al. 15-year experience with the Carpentier-Edwards pericardial bioprosthesis. Ann Thorac Surg. 1998;66:S57-61. (Freedom from structural deterioration; n = 214; mean age = 65 ± 23 yrs)
5. Neville, PH, et al. Carpentier-Edwards pericardial bioprosthesis in aortic, PH or mitral position: a 12-year experience. Ann Thorac Surg. 1998;66(6 Suppl):S143-7. (Freedom from structural deterioration; n = 182; mean age = 63.9 ± 11.5 years)
6. Marchand, MA, et al. Fifteen-year experience with the mitral Carpentier-Edwards PERIMOUNT pericardial bioprosthesis. Ann Thorac Surg. 2001 May;71(5 Suppl):S236-9. (Freedom from structural valve deterioration; n = 435; mean age = 60.7 ± 11.6 yrs)
7. Carpentier-Edwards PERIMOUNT pericardial bioprosthesis 16-year results. Data on file at Edwards Lifesciences, 2003. (Freedom from explant due to structural valve deterioration; n = 404 mean age = 60.7 ± 11.6 yrs)
8. Bourguignon, T, et al. Very late outcomes for mitral valve replacement with the Carpentier-Edwards pericardial bioprosthesis: 25 year follow-up of 450 implantations. J Thorac Cardiovasc Surg. 2014 Nov;148:2004-11. (Freedom from explant due to structural valve deterioration; n = 404; mean age = 68.0 ± 10.4 yrs)

#### Brief Summary: Mitral Bioprostheses

Indications: For use in patients whose mitral valvular disease warrants replacement of their natural or previously placed prosthetic valve and when the valve cannot be repaired. Contraindications: Do not use if surgeon believes it would be contrary to the patient's best interests. Complications and Side Effects: Stenosis, regurgitation, endocarditis, hemolysis, thromboembolism, valve thrombosis, nonstructural dysfunction, structural valve deterioration, anemia, arrhythmia, hemorrhage, transient ischemic attack/ stroke, congestive heart failure, myocardial infarction, angina, ventricular perforation by stent posts, any of which could lead to reoperation, explantation, permanent disability and death. Warnings: Alternative therapies should be considered in the presence of conditions affecting calcium metabolism or when calcium containing chronic drug therapies are used, including children, adolescents, young adults and patients on a high calcium diet or maintenance hemodialysis. Should be used with caution in the presence of severe systemic hypertension or when anticipated patient longevity is longer than the known longevity of the prosthesis.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. See the Instructions for Use for a full description of prescribing information.

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