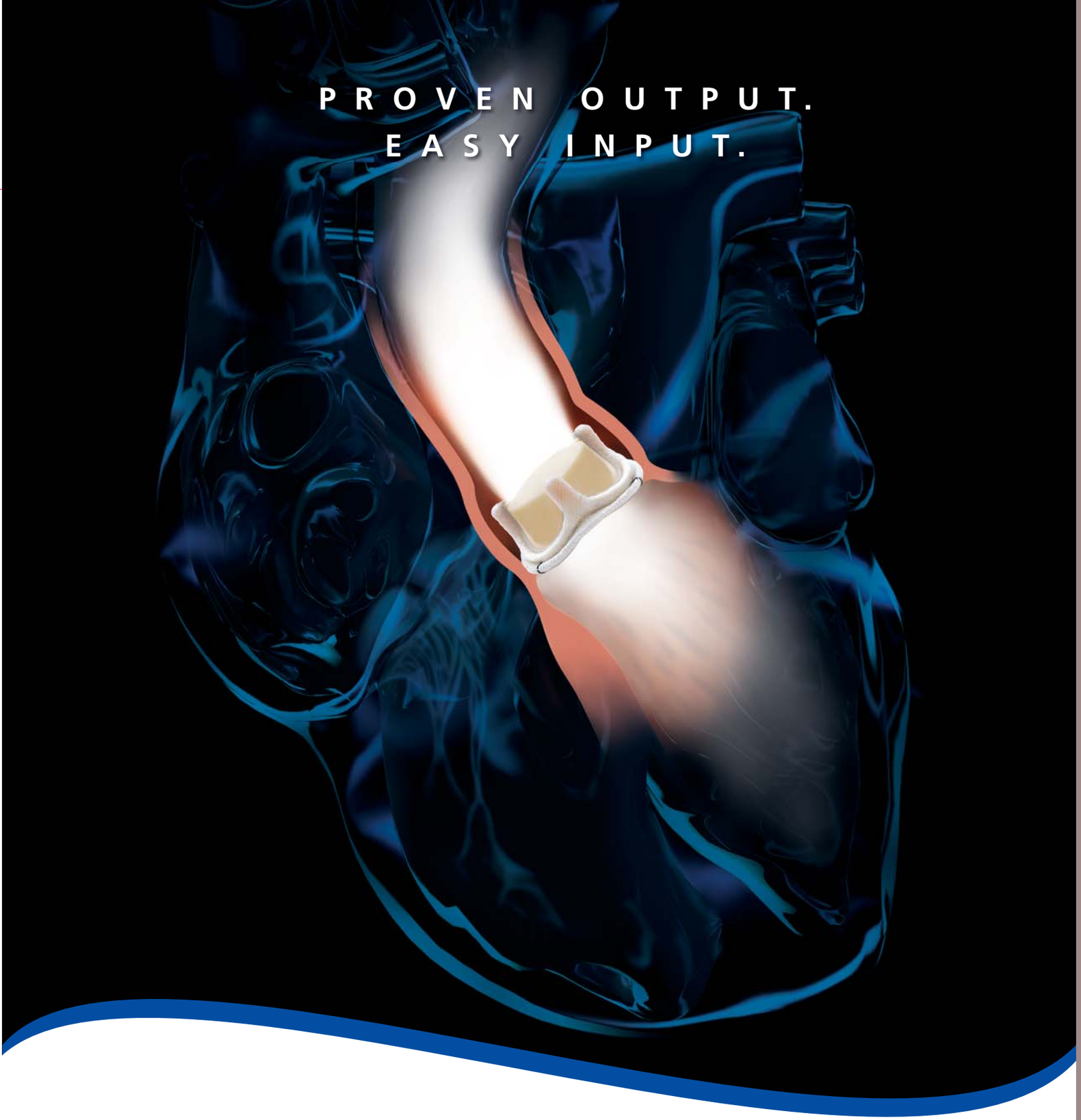


CARPENTIER-EDWARDS PERIMOUNT

MAGNA EASE

PERICARDIAL AORTIC BIOPROSTHESIS

Edwards
LIFESCIENCES

Proven superior hemodynamics

- Industry-leading EOAs and low gradients documented in multiple published studies[1-7]
- Based on a proven design with published hemodynamic stability up to 17 years post-implantation[8]

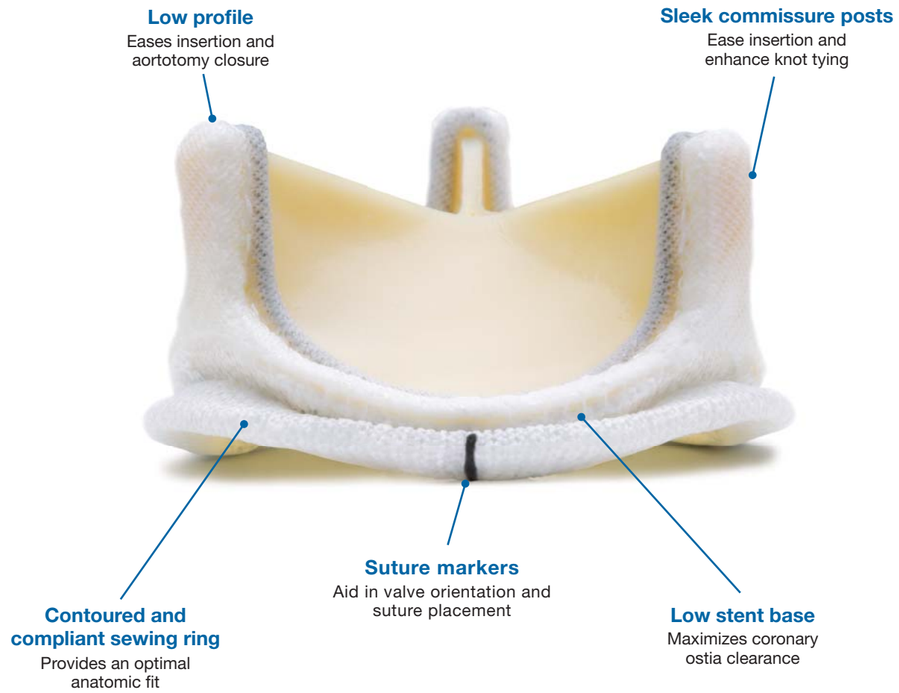
Designed for endurance

- Built on the proven performance of PERIMOUNT aortic valves, with over 27 years of clinical experience[9,10]
- Commissural stress points minimized by mounting matched leaflets under the stent
- The Carpentier-Edwards ThermaFix process* is the only anti-calcification technology designed to confront both major calcium binding sites

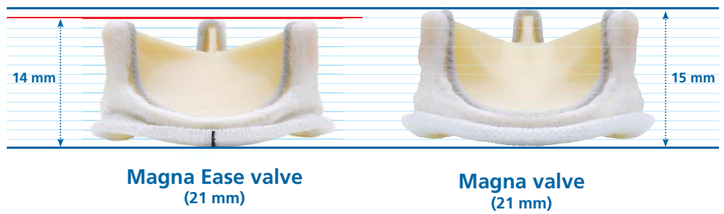
*No clinical data are available which evaluate the long-term impact of the Edwards Lifesciences tissue treatment in patients.

Where MAGNA hemodynamics meets EASE of implantation.

The advanced Carpentier-Edwards PERIMOUNT Magna Ease aortic valve adds enhanced implantability to the unsurpassed hemodynamics[1-7] of the Magna valve platform — setting the new standard for tissue valve performance.



Lowered for ease of implantation



Ease of implantation

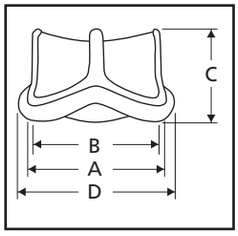
- Eased insertion through small incisions or small aortic roots due to low valve profile and sleek commissure posts
- Maximized coronary ostia clearance achieved with low stent base
- Optimized valve seating due to contoured and compliant sewing ring
- Aided valve orientation and suture placement with three mid-commissure suture markers on the sewing ring

- Enhanced knot tying achieved with sleek commissure posts
- Eased aortotomy closure as a result of low profile design

Magenta keyline does not print. Indicates top of pocket.

Carpentier-Edwards PERIMOUNT Magna Ease Pericardial Aortic Bioprosthesis

Model 3300TFX Nominal Specifications (mm)



Size	19 mm	21 mm	23 mm	25 mm	27 mm	29 mm
A. Stent Diameter	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

Accessories

- Unique dual-ended sizer, model 1133 available in sizes 19-29 mm
- Reusable handle, model 1111
- Longer single-use handle, model 1126
- Tray for sizers and handles, model TRAY1133

References

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9. Carpentier-Edwards PERIMOUNT aortic pericardial bioprosthesis 20-year results. Data on file at Edwards Lifesciences, 2003.
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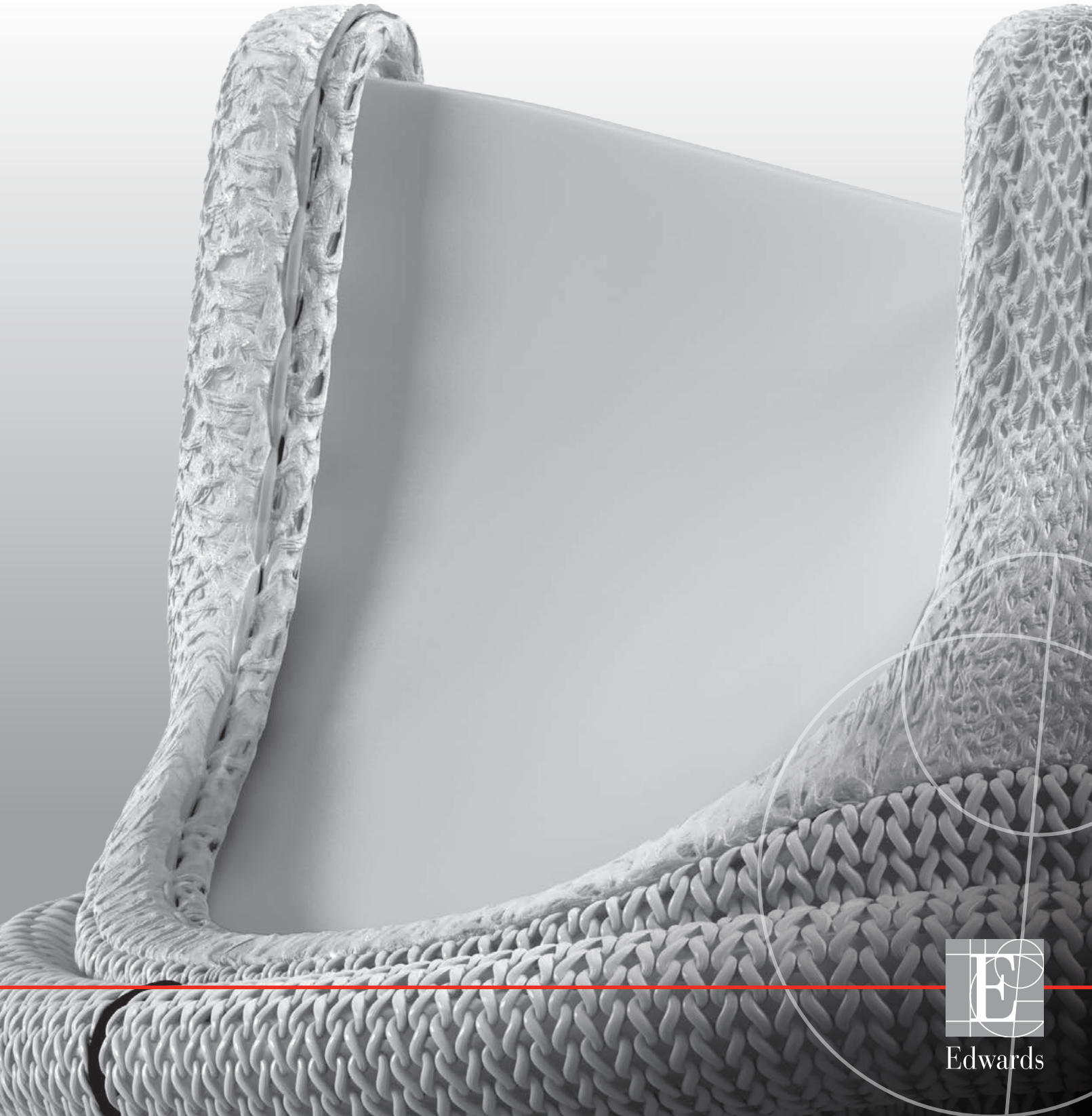
CARPENTIER-EDWARDS PERIMOUNT

MAGNA EASE

PERICARDIAL AORTIC BIOPROSTHESIS

WHEN THE MOMENT MATTERS:

MAKE THE CHOICE YOU WOULD MAKE FOR YOURSELF



Edwards

CARPENTIER-EDWARDS PERIMOUNT

MAGNA EASE

PERICARDIAL AORTIC BIOPROSTHESIS

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

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

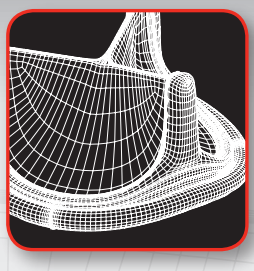
- Excellent & stable **Hemodynamics**
- Exceptional **Long-Term Durability**
- A low profile, supra-annular valve that is **Easy to Implant**

It is no wonder that surgeons choose the Magna Ease valve more than any other.

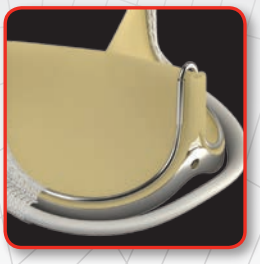
It all starts with the

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**



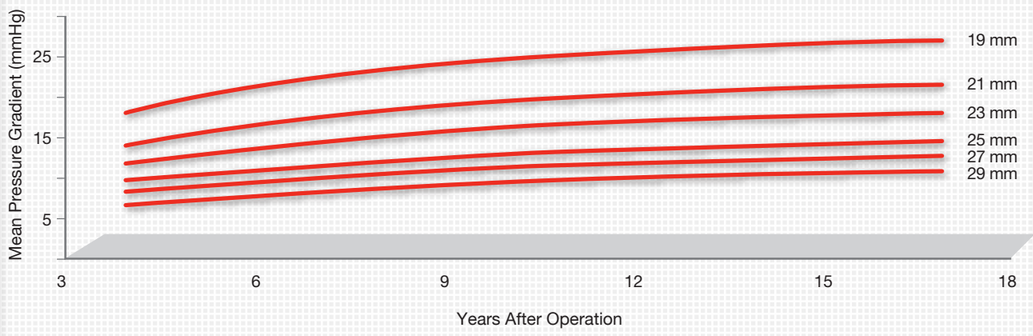
- **Flexible cobalt-chromium alloy stent**
  Absorbs energy to reduce leaflet stress

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

EXCELLENT AND STABLE HEMODYNAMICS

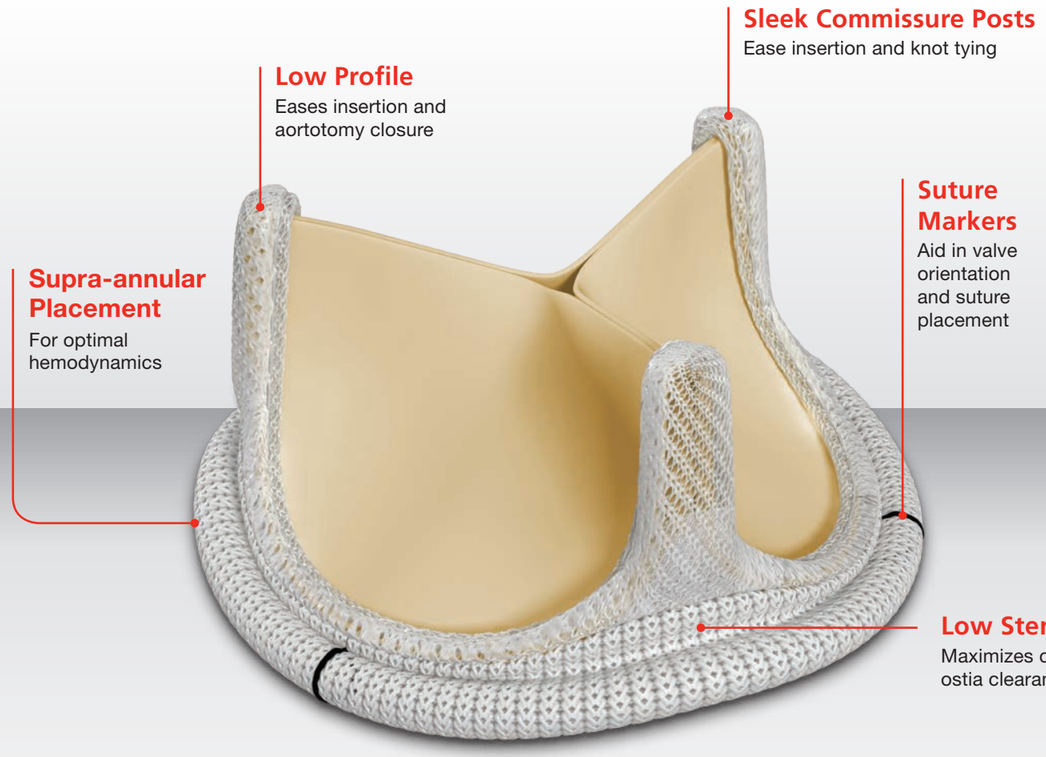
- Excellent EOAs and low gradients documented in published studies[1-3]
- Documented hemodynamic stability up to 17 years post-implantation

Change in PERIMOUNT Aortic Bioprostheses Gradients Over Time[4]



EASE OF IMPLANT

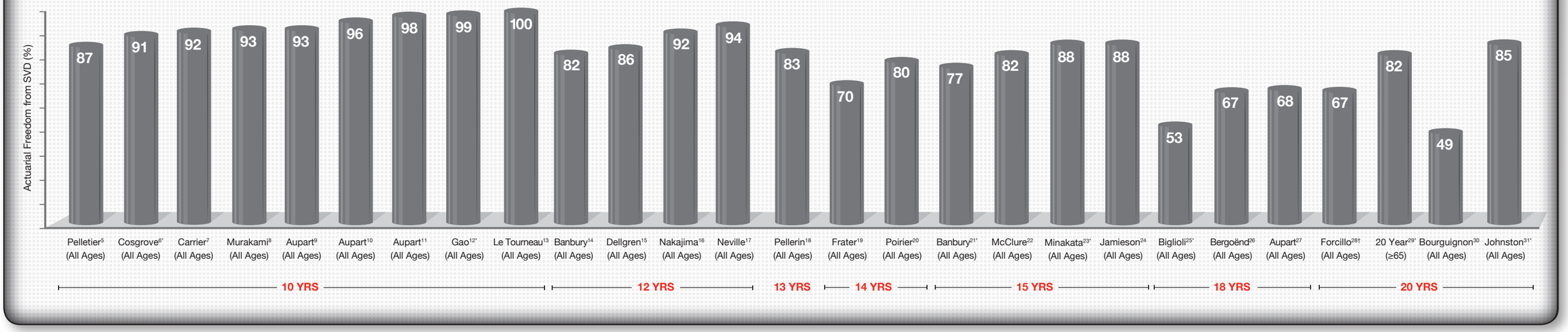
- Offers many key design features that enhance the valve's ease of implant



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 *PERIMOUNT Aortic Bioprostheses*



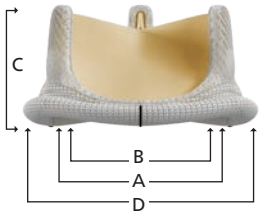
Methodology: Comprehensive literature searches were conducted utilizing a combination of key words. See references section for key words, filters, and a search results summary.

* Freedom from explant / prosthesis replacement / reoperation due to SVD
† Freedom from valve reoperation for prosthesis dysfunction and all other causes

REFERENCES

To learn more about the Magna Ease valve, please contact your Edwards Lifesciences sales representative, or visit edwards.com.

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*

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REFERENCES FOR THE CARPENTIER-EDWARDS PERIMOUNT MAGNA EASE VALVE BROCHURE

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7. Carrier M, Pellerin M, Perrault LP, et al. Aortic Valve Replacement with Mechanical and Biologic Prosthesis in Middle-aged Patients. Ann Thorac Surg. 2001;71:S253-256. (Cohort size = 158, mean age = 61 ± 3 yrs. Number at risk for Valve Dysfunction at last follow-up not reported)
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20. Poirier NC, et al. 15-year Experience with the Carpentier-Edwards Pericardial Bioprosthesis. Ann Thorac Surg. 1998;66:S57-61. (Cohort size = 598, mean age = 65 yrs. Number at risk for Structural Deterioration at last follow-up = 8)
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28. 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)

29. 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)

30. Bourguignon T et al. Very Long-Term Outcomes of the Carpentier-Edwards Perimount Valve in Aortic Position. The Annals of Thoracic Surgery. doi:10.1016/j.athoracsur.2014.09.030. (Cohort size = 2,659, mean age = 71 yrs. Number at risk for Structural Deterioration at last follow-up = 27)

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PERIMOUNT Aortic Literature Search Methodology and References

Methodology: Comprehensive literature searches were conducted utilizing a combination of key words: "Carpentier-Edwards," "PERIMOUNT," "aortic," "structural valve deterioration/degeneration" and "durability." The searches resulted in 490 unique citations published between 1977-2014. The citations were filtered for English language article, clinical study, human study, full-text article, on-indication use, non-transcatheter and PERIMOUNT aortic valves as primary study premise. Single patient or small case studies, foreign language publications, duplications, meta-analyses, in-vitro studies, cadaver studies were excluded. This resulted in 25 unique, relevant articles published on the PERIMOUNT aortic valve durability. Additionally, the Edwards' 20 Year Clinical Communique on PERIMOUNT durability was included.

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EC CERTIFICATE

Number: 2103732CE04

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III and Devices in Class I with measuring function and in sterile condition)

Manufacturer:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

For the product category(ies)

Biological Heart Valve Substitutes and Accessories and Pericardial Patches for Use in Heart Surgery

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2103732CN, initially dated 31 August 2007
Addendum, initially dated 31 March 2010

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection, that covers the aspects of manufacture concerned with the conformity of the devices with metrological requirements and with securing and maintaining sterile conditions, for the above mentioned product category in accordance to the provisions of Annex II Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. Additionally, DEKRA hereby declares that the manufacturer fulfils the relevant provisions as specified in Annex I of Commission Regulation 722/2012 of 8 August, 2012 concerning medical devices manufactured utilising tissue of animal origin. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory.
The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until:	26 May 2024	Revised:	16 July 2019
Issued for the first time:	31 March 2010	Reissued:	1 October 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2103732CE04

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Biological Heart Valve Substitutes and Accessories and Pericardial Patches for Use in Heart Surgery

Issued to:

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614
United States Of America

This certificate covers the following product(s):

Heart Valves, Animal Origin: Biological Heart Valve Substitutes and Accessories (Class III)
- Carpentier-Edwards PERIMOUNT Bioprosthesis Aortic and Mitral Heart Valves
- EDWARDS INTUITY Valves (aortic)
- EDWARDS INTUITY Delivery Systems
- Edwards Inflation Device (Class Is/ Im)

Patch of Animal Origin: Pericardial Patches (Class III)

Initial date: 31 March 2010
Revision date: 16 July 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

CERTIFICATE

Number: 3821948

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

including the implementation meets the requirements of the standard:

ISO 13485:2016
EN ISO 13485:2016

Scope: Design, development, production and distribution of:

- biological surgical heart valves and accessories (delivery system and inflation device, handles, sizers, trays, suture fasteners, heart support device);
- transcatheter heart valve systems (biological heart valves, delivery systems, balloon catheters) and accessories (access devices, inflation devices and crimpers);
- transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate);
- annuloplasty rings and accessories (handles, sizers, and trays);
- biologic pericardial patches for the area of heart valve replacement, repair and reconstruction;
- catheters, cannula and occlusion devices and accessories (introducer sheaths, percutaneous insertion kits.

Certificate expiry date: 7 January 2024
Certificate effective date: 8 June 2021
Certified since: 13 December 2018

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

MGMT. SYS. RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

To certificate: 3821948

The management system of the organization(s) and/or location(s) of:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

Certified organization(s) and/or locations:

Location	Certification scope / Activity
Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA	Design, development, production and distribution of: • biological surgical heart valves and accessories (delivery system and inflation device, handles, sizers, trays, suture fasteners, heart support device); • transcatheter heart valve systems (biological heart valves, delivery systems, balloon catheters) and accessories (access devices, inflation devices and crimpers); • transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate); • annuloplasty rings and accessories (handles, sizers, and trays); • biologic pericardial patches for the area of heart valve replacement, repair and reconstruction; • catheters, cannula and occlusion devices and accessories (introducer sheaths, percutaneous insertion kits.
Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020 USA	Production and distribution of: • biological surgical heart valve accessories (delivery system and inflation device, handles, sizers, trays, suture fasteners, heart support device); • transcatheter heart valve systems (biological heart valve delivery systems, balloon catheters) and accessories (access devices, inflation devices and crimpers); • transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate); • annuloplasty rings and accessories (handles, sizers, and trays); • catheters, cannula and occlusion devices and accessories (introducer sheaths, percutaneous insertion kits.

ADDENDUM

To certificate: 3821948

The management system of the organization(s) and/or location(s) of:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

Certified organization(s) and/or locations: continued

Location	Certification scope / Activity
Edwards Lifesciences (Singapore) Pte Ltd 35 Changi North Crescent Singapore 499641 Singapore	Production and distribution of: • biological surgical heart valves; • transcatheter heart valve systems; • transcatheter valve repair and replacement systems (implants).
Edwards Lifesciences Costa Rica S.R.L. La Lima Zona Franca, Edificio Multitenant Modulos 1-3, La Lima, Cartago, Costa Rica	Production and distribution of: • biological heart valve replacement subassemblies.
Edwards Lifesciences Costa Rica S.R.L. Zona Franca La Lima de la entrada de Pequeño Mundo 100 mts oeste y 200 mts sur, Finca 31 y 32, Guadalupe Cartago, Costa Rica	Production and distribution of: • transcatheter heart valves.
Edwards Lifesciences LTD 10 Earhart Ave Shannon Industrial Estates Shannon, County Clare V14 P638 Ireland	Production and distribution of: • transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate).

Addendum expiry date: 7 January 2024
Addendum effective date: 8 June 2021

Edwards

EC Declaration of Conformity

Manufacturer:	*Edwards Lifesciences LLC* *One Edwards Way* *Irvine, CA 92614, USA*
European Representative:	*Edwards Lifesciences Services GmbH* *Edisonstrasse 6* *85716 Unterschleissheim, Germany*
Product category:	*07 – Non-active implantable devices* *(according to EN ISO 15225)*
Products:	***Biological Heart Valve Substitutes*** *Model codes, Names: see following pages*
Classification:	*Class III / Rules 8 and 17* *(According to Annex IX of the MDD)*
Conformity Assessment Route:	*Annex II*
UMDNS / GMDN Nomenclature:	*UMDNS: 15870 Prostheses, Cardiac Valve, Biological* *GMDN: 60242 Aortic Heart Valve Bioprosthesis* *60244 Mitral Heart Valve Bioprosthesis*
Applicable Standards:	*The harmonized standards and other consensus standards used (specified by numbers, titles, editions and/or dates of issue) in relation to which conformity is declared, as well as the identification of internal data confirming compliance are provided in the Essential Requirements Checklists for the products identified in this declaration.*
Start of CE Marking:	*See following pages*

We herewith declare that the distributed CE marked products specified above conform to the products covered by the "CE Marking of Conformity Certificate" issued and delivered by DEKRA Certification B.V., in accordance with Annex II of the "EC-Directive," Council Directive 93/42/EEC of 14 June 1993, concerning Medical Devices and with the particular requirements laid down in Annex I of Commission Regulation 722/2012 of 8 August, 2012, concerning medical devices manufactured utilizing tissue of animal origin. All supporting documentation is retained at the premises of the manufacturer.

In addition, we ensure and declare that the distributed CE marked products meet the provisions of the EC-Directives that apply to them. This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive. The conformity of the full quality assurance system is described in the said CE Marking of Conformity Certificate, issued and delivered by DEKRA Certification B.V.

The manufacturer has established and is maintaining a quality system which meets the requirements of the international standards indicated in the table below.

These directive(s) and standard(s) are supported by the following certificates:

Certificate Number	Valid until	Issued by	Holder of Certificate	Facility(ies)
3817373 ISO 13485:2016	2021-01-07	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine	One Edwards Way Irvine, CA 92614, USA 17192 Daimler Irvine, CA 92614, USA 12050 Lone Peak Parkway Draper, UT 84020, USA 35 Changi North Crescent Singapore 499641 Singapore 1821 Kettering Irvine, CA 92614, USA La Lima Zona Franca, Edificio Multitenant Modulos 1-3, La Lima, Cartago, Costa Rica
3821948 ISO 13485:2016 EN ISO 13485:2016	2021-01-07	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine	One Edwards Way Irvine, CA 92614, USA 17192 Daimler Irvine, CA 92614 USA 1821 Kettering Irvine, CA 92614 USA 12050 Lone Peak Parkway Draper, UT 84020 USA 35 Changi North Crescent Singapore 499641 Singapore La Lima Zona Franca, Edificio Multitenant Modulos 1-3, La Lima, Cartago, Costa Rica
2103732CE04	2024-05-26	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine	One Edwards Way Irvine, CA 92614, USA
2103732DE04	2024-05-26	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine	One Edwards Way Irvine, CA 92614, USA

Notified Body:

DEKRA Certification B.V
Meander 1051

6825 MJ Arnhem, The Netherlands
Identification Number 0344

Trade Name and Sizes	Model(s)	Start of CE Marking
Carpentier-Edwards® PERIMOUNT RSR® Pericardial Bioprosthesis [aortic] *Sizes: 19, 21, 23, 25, 27, 29 mm*	2800TFX	April 2019
Carpentier-Edwards® PERIMOUNT Plus® Pericardial Bioprosthesis [mitral] *Sizes: 25, 27, 29, 31, 33 mm*	6900PTFX	April 2004
Carpentier-Edwards® PERIMOUNT® Magna Ease™ Pericardial Bioprosthesis [aortic] *Sizes: 19, 21, 23, 25, 27, 29 mm*	3300TFX	Dec 2006
Carpentier-Edwards® PERIMOUNT® Magna Mitral Ease™ Pericardial Bioprosthesis [mitral] *Sizes: 25, 27, 29, 31, 33 mm*	7300TFX	Aug 2010

This declaration of conformity is issued under the sole responsibility of Edwards Lifesciences LLC.

Signed for and on behalf of
Manufacturer: *Edwards Lifesciences LLC*

Ashwini Jacob

Digitally signed by Ashwini Jacob
DN: cn=Ashwini Jacob, o=Edwards Lifesciences, ou=Sr. Director, Regulatory Affairs, email=ashwini_jacob@edwards.com, c=US
Date: 2019.09.30 16:08:23 -07'00'

Ashwini Jacob
Sr Director, Regulatory Affairs