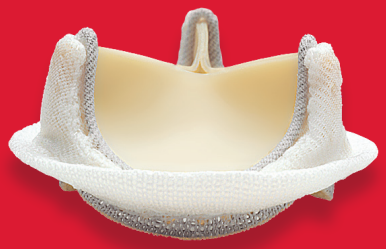
Carpentier-Edwards PERIMOUNT RSR Pericardial Aortic Bioprosthesis



Model 2800TFX

Bioengineered PERIMOUNT valve technology

Since its introduction in 1981, the PERIMOUNT valve has proven its long-term performance, based on key elements designed to optimize hemodynamics and valve durability[1-4]:

- Three independent symmetrical pericardial leaflets are matched for thickness and elasticity for long-term endurance and full valve opening
- Leaflets are mounted under the flexible stent to transfer stress during the cardiac cycle from the tissue to the stent
- Flexible cobalt-chromium stent absorbs and distributes stress evenly to minimize fatigue areas

The PERIMOUNT bioprosthesis design has been in clinical use for more than 38 years

Indications

The Carpentier-Edwards PERIMOUNT RSR (Reduced Sewing Ring) pericardial aortic bioprosthesis is intended for use in patients whose aortic valvular disease is sufficiently advanced to warrant replacement of their natural valve with a prosthetic one. It is also intended for use in patients with a previously implanted aortic valve prosthesis that is no longer functioning adequately and requires replacement. In the latter case, the previously implanted prosthesis is surgically excised and replaced by the replacement prosthesis.

Tissue Treatment*

The PERIMOUNT valve is treated with the Carpentier-Edwards ThermaFix* process, which confronts both major calcium binding sites: residual glutaraldehydes and phospholipids.

Progressive tissue calcification is indeed the main cause of failure of biological valves[5]. By removing potential calcium binding sites, tissue treatment has been shown to reduce the risk of structural valve deterioration (SVD)[6].

General Product Information

- **Storage Temperature:** 10°C to 25°C
- **Storage Solution:** Glutaraldehyde
- **Rinse Procedure:**
  500 ml (sterile physiological saline solution) x 60 seconds
  repeat once using new saline solution
- **MRI Safety Information:** A patient with the valve can be scanned safely, the following conditions: Static magnetic field of 3 tesla or less, spatial gradient field of less than 3000 gauss/cm and maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg in the normal operating mode for 15 minutes of MR scanning per sequence.

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

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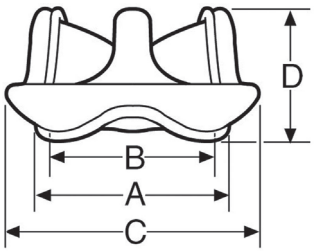
Specifications

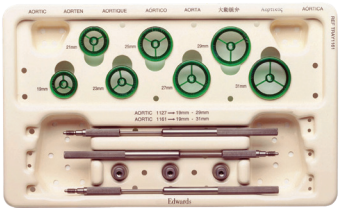


Modele 2800TFX

Size	19 mm	21 mm	23 mm	25 mm	27 mm	29 mm
A. Mounting Diameter (Annulus)	19	21	23	25	27	29
B. Internal Diameter (Stent I.D.)	18	20	22	24	26	28
C. External Sewing Ring Diameter	26	28	31	32	35	37
D. Total Profile Height	14	15	16	17	18	19

Significant dimensions in millimeters (nominal values)

Sizers and Accessories

Model 1161SET	Complete sizer set	
Model 1111	Reusable handle	
Model 1126	Single-use handle (extended length)	

References

1. 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.
2. 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.
3. 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.
4. Wagner IM, et al. Influence of completely supra-annular placement of bioprostheses on exercise hemodynamics in patients with a small aortic annulus. *J Thorac Cardiovasc Surg* 2007;133(5):1234-41.
5. Schoen FJ et al Calcification of Tissue Heart Valve Substitutes: Progress *Toward Understanding and Prevention Ann Thorac Surg* 2005;79:1072– 8.
6. Flameng et al. Antimineralization treatment and patient-prosthesis mismatch are major determinants of the onset and incidence of structural valve degeneration in bioprosthetic heart valves. *J Thorac Cardiovasc Surg* 2014 Apr;147(4):1219-24

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

Edwards Lifesciences devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Edwards Lifesciences • Route de l'Etraz 70, 1260 Nyon, Switzerland • edwards.com

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 039555 0207 Rev. 00

Holder of Certificate: **Edwards Lifesciences LLC**
One Edwards Way
Irvine CA 92614
USA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Hemodynamic Monitoring Equipment, Disposables and Related Accessories;
Medical Devices used for the Diagnosis of Coronary Artery Disease;
Medical Devices and Related Accessories used in the Diagnosis and Treatment of Peripheral Vascular Disease;
Medical Devices used in Support of Cardiopulmonary Bypass Surgery;
EtO Sterilization Services and Respective Microbiological and Chemical Tests (Añasco)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 72157269

Valid from: 2020-06-07
Valid until: 2023-06-06

Date, 2020-05-14

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 039555 0207 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Edwards Lifesciences Technology Sàrl
State Road 402, Km 1.4, Industrial Park, 00610-1577 Añasco, PUERTO RICO USA

Edwards Lifesciences AG, Parque Industrial Itabo
Km 18.5 CARR.Sanchez, Haina, San Cristobal, DOMINICAN REPUBLIC

Parameters:

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

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

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T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2103732DE04

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

For the product

Heart Valves, Animal Origin: Biological Heart Valve Substitutes

Documents, that form the basis of this certificate:

Certification Notice 2103732CN, initially dated 31 August 2007
CE Marking of Conformity 2103732CE04
Addendum, initially dated 31 March 2010

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, 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, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of 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.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 31 March 2010
Revised: 4 January 2019
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

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T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2103732DE04

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Heart Valves, Animal Origin: Biological Heart Valve Substitutes

Issued to:

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

This certificate covers the following product(s):

Device Model	Description
2800TFX	Carpentier-Edwards® PERIMOUNT RSR® Pericardial Aortic Bioprosthesis Sizes 19, 21, 23, 25, 27, 29mm
3300TFX	Carpentier-Edwards® PERIMOUNT® Magna Ease Pericardial Aortic Bioprosthesis Sizes: 19, 21, 23, 25, 27 and 29mm
6900PTFX	Carpentier-Edwards® PERIMOUNT Plus® Mitral Bioprosthesis Sizes: 25, 27, 29, 31 and 33mm
7300TFX	Carpentier-Edwards® PERIMOUNT® Magna Mitral Ease™, Pericardial Bioprosthesis [mitral] Sizes: 25, 27, 29, 31 and 33 mm
11000A	Edwards® Pericardial Aortic Bioprosthesis Sizes 19, 21, 23, 25, 27 and 29mm
11000M	Edwards® Pericardial Mitral Bioprosthesis Sizes 25, 27, 29, 31, 33mm
11500A	INSPIRIS RESILIA™ Aortic Valve Sizes 19, 21, 23, 25, 27 and 29mm

Initial date: 31 March 2010
Revision date: 14 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

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T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

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