Carpentier-Edwards Physio Annuloplasty Ring

The #1 clinically proven annuloplasty ring.

Edwards LIFESCIENCES

The Gold Standard for remodeli

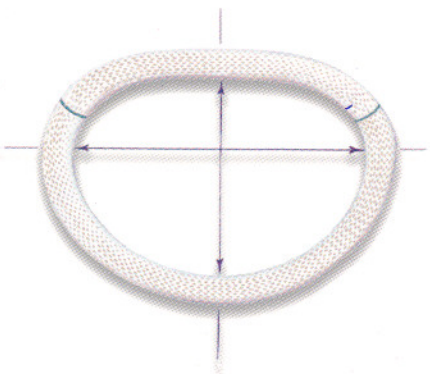
Carpentier-Edwards Physio Annuloplasty Ring

The low incidence of reoperation and late cardiac events suggest that the Carpentier-Edwards Physio annuloplasty ring, with its inherent flexibility, offers a definite advantage in the application of remodeling techniques in mitral valve reconstruction.[1]

DESIGNED TO BE THE BEST OF BOTH WORLDS

Semirigid Flexibility

- Variable flexibility is created by the movement of Elgiloy bands separated by plastic bands.
- Allows for ***Physio***logic contractility of the mitral valve annulus during systole.
- Minimizes stress on sutures.



Remodeling

- Preserves natural 3:4 ratio between the anteroposterior diameter and transverse diameter during systole.
- Restores anatomical size and shape to provide optimal orifice area.

Based on a 25-year experience, the Carpentier-Edwards Physio annuloplasty ring incorporates all of the features mandatory for a physiological and durable repair of the mitral valve annulus.[2]

ng while preserving flexibility

PHYSIOLOGIC ANATOMICAL CONFORMANCE

- The original saddle shape to better fit ***Physio***logic dimensions while remodeling the annulus to its anatomic shape.
- Conforms to the configuration of the normal mitral annulus.

Mitral valve reconstruction is the treatment of choice for most patients with regurgitant lesions.[1]

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The #1 clinically proven annuloplasty ring.

I.	492 Patients	These findings support the continued use of the Carpentier-Edwards Physio annuloplasty ring in patients presenting with mitral insufficiency secondary to degenerative disease of the mitral valve as well as in the clinical setting of ischemic mitral insufficiency.[1]
II.	190 Patients	The Carpentier-Edwards Physio annuloplasty ring provided reliable and stable results at medium-term follow-up with a very low incidence of valve-related complications.[3]
III.	137 Patients	Based on a 25-year experience, the Carpentier-Edwards Physio annuloplasty ring incorporates all of the features mandatory for a physiological and durable repair of the mitral valve annulus.[2]
IV.	100 Patients	The authors conclude that the Carpentier-Edwards Physio annuloplasty ring enables reliable and effective mitral valvuloplasty with excellent short-term results.[4]
V.	51 Patients	Excellent results of combined restrictive annuloplasty and CABG were obtained.[5]
VI.	30 Patients	The findings from this study indicated a low incidence of device-related complication, while excellent valvular function was maintained.[6]

Helping patients is our life's work, and *life is now*

Carpentier-Edwards Physio Annuloplasty Ring — The Gold Standard

The Carpentier-Edwards Physio annuloplasty ring can play a critical role in the operative management of patients presenting with mitral valve disease.[1]

Model Description	Model Number
Carpentier-Edwards Physio annuloplasty ring (Sizes 24 mm-40 mm)	4450
Handle	1150
Extended handle (total length 10.4 inches)	1151
Mitral sizers	1174
Handle for sizers (reusable)	1111
Handle for sizers (single use)	1126

References:

1. Accola KD, Scott ML, Thompson PA, et al. Midterm outcomes using the physio ring in mitral valve reconstruction: experience in 492 patients. *Ann Thorac Surg.* 2005;79(4):1276-83.
2. Carpentier AF, Lessana A, Relland JY, et al. The "Physio-Ring": An Advanced Concept in Mitral Valve Annuloplasty. *Ann Thorac Surg.* 1995;60:1177-1185.
3. Raffoul R, Uva MS, Rescigno G, et al. Clinical evaluation of the Physio annuloplasty ring. *Chest* 1998 May;113(5):1296-301.
4. Sousa Uva M, Raffoul R, Belli E, et al. Initial results of mitral valvuloplasty using the Physio-Carpentier-Edwards ring. *Arch Mal Coeur Vaiss.* 1997 Jun;90(6):789-95.
5. Bax JJ, Braun J, Somer ST , et al. Restrictive Annuloplasty and Coronary Revascularization in Ischemic Mitral Regurgitation Results in Reverse Left Ventricular Remodeling. *Circulation.* 2004;110:II-103 – II-108.
6. Kurosawa H, Nakano M, Kawase M, et al. Mitral valve repair by Carpentier-Edwards physio annuloplasty ring. *Jpn J Thorac Cardiovasc Surg.* 1999 Aug;47(8):355-60.

Edwards Lifesciences

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ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039555 0201 Rev. 00

Manufacturer: **Edwards Lifesciences LLC**
One Edwards Way
Irvine CA 92614
USA

Product Category(ies): **Prosthetic Rings for Treatment of Heart Valve Insufficiency**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72151203

Valid from: 2020-03-03
Valid until: 2024-05-26

Date, 2020-03-03

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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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

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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

Legal Manufacturer:	*Edwards Lifesciences LLC* *One Edwards Way* *Irvine, CA 92614, USA*
Manufacturing Site(s):	*Edwards Lifesciences LLC* *12050 Lone Peak Parkway* *Draper, UT 84020 USA*
European Representative:	*Edwards Lifesciences Services GmbH* *Edisonstrasse 6* *85716 Unterschleissheim, Germany*
Product(s):	***Annuloplasty Rings*** *Model codes, Names: see following pages*
Product category:	***Cardiovascular Implants*** ***Prosthetic Rings for Treatment of Heart Valve Insufficiency*** *07 – Non-active implantable devices* *(according to EN ISO 15225)*
Classification:	*Class III / Rule 8* *(According to Annex IX of the MDD)*
Conformity Assessment Route:	*Annex II*
UMDNS / GMDN Codes:	*UMDNS: 16039 Annuloplasty Rings* *GMDN: 45577 Mitral Annuloplasty Ring* *GMDN: 45578 Mitral / Tricuspid Annuloplasty Ring*

We hereby declare that the distributed CE marked products specified in the attached product list, meet the provisions of the “EC-Directive”, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and any subsequent amendments. In addition, we declare that the listed products conform to applicable standards and the essential requirements listed in Annex I of the Directive. All supporting documentation is retained under the control of the Legal Manufacturer.

In addition, we ensure and declare that the distributed CE marked products meet the provisions of the EC-Directive that applies 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 TÜV SÜD Certification.

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80399 Münich Germany Identification Number 0123

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

The directive and these standards are supported by the following certificates:

Certificate Number	Valid until	Issued by	Holder of Certificate
3821948 ISO 13485:2016 EN ISO 13485:2016	2021-01-07	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine
3817373 ISO 13485:2016	2021-01-07	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine
G1 039555 0201, Rev. 00	2024-05-26	TÜV SÜD Product Service GmbH	Edwards Lifesciences LLC, Irvine
G7 039555 0206, Rev. 00	2024-05-26	TÜV SÜD Product Service GmbH	Edwards Lifesciences LLC, Irvine

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

Signed for and on behalf of Manufacturer
Signature and Date of Issue:

Debra Grodt

Digitally signed by Debra Grodt
DN: cn=Debra Grodt, o=Edwards Lifesciences, ou=Regulatory Affairs Director, email=debra_grodt@edwards.com, c=US
Reason: I am approving this document
Date: 2020.03.03 07:13:51 -08'00'

Debra Grodt *Date*
Director, Regulatory Affairs
Edwards Lifesciences LLC
Irvine, CA

Product List: Edwards Annuloplasty Rings

Trade Name and Sizes	Model(s)	Start of CE Marking
Carpentier-McCarthy-Adams IMR ETlogix Annuloplasty Ring Mitral Model 4100 with Holder *Sizes*: *24, 26, 28, 30, 32, 34 mm*	4100	02 Dec 2003
Carpentier-Edwards Physio Annuloplasty Ring Mitral with Holder *Sizes*: *24*, *26, 28, 30, 32, 34, 36, 38, 40 mm*	4450	08 May 2000
Cosgrove-Edwards Annuloplasty System with Template/Lanyard for Valvuloplasty *Sizes*: *26, 28, 30, 32, 34, 36, 38 mm*	4600	08 May 2000
Edwards MC3 Tricuspid Annuloplasty Ring with Template/Lanyard for Valvuloplasty *Sizes*: *26, 28, 30, 32, 34, 36 mm*	4900	15 July 2002
Carpentier-Edwards Physio II Annuloplasty Ring *Sizes*: *24*, *26, 28, 30, 32, 34, 36, 38, 40 mm*	5200	17 Oct 2008
Carpentier-Edwards Physio Tricuspid Annuloplasty Ring Model 6200 *Sizes*: *24*, *26, 28, 30, 32, 34, 36 mm*	6200	23 May 2011