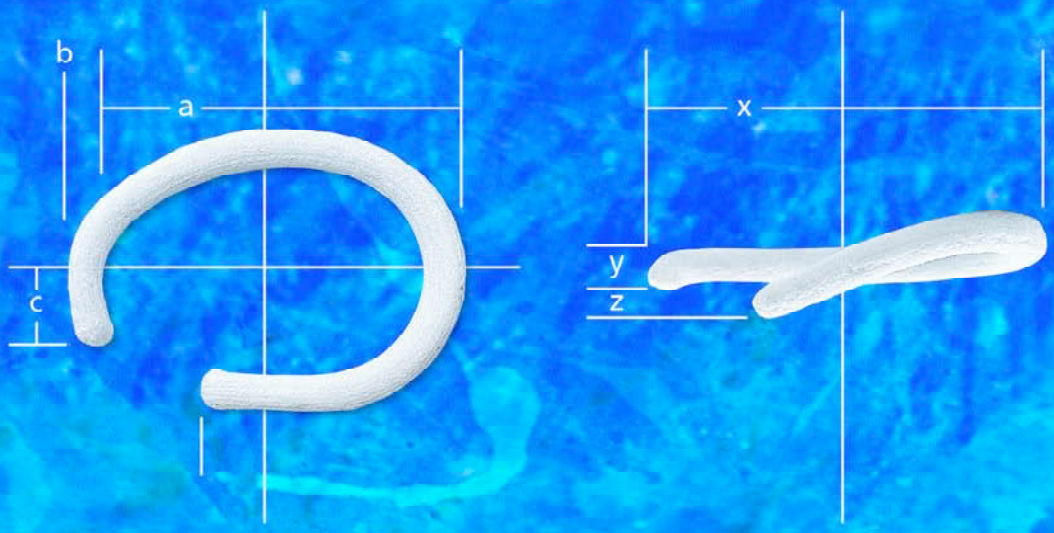
Taking proven geometry
to a new dimension.



The Edwards MC³ Tricuspid Annuloplasty System.
The only 3-D ring for tricuspid repair.

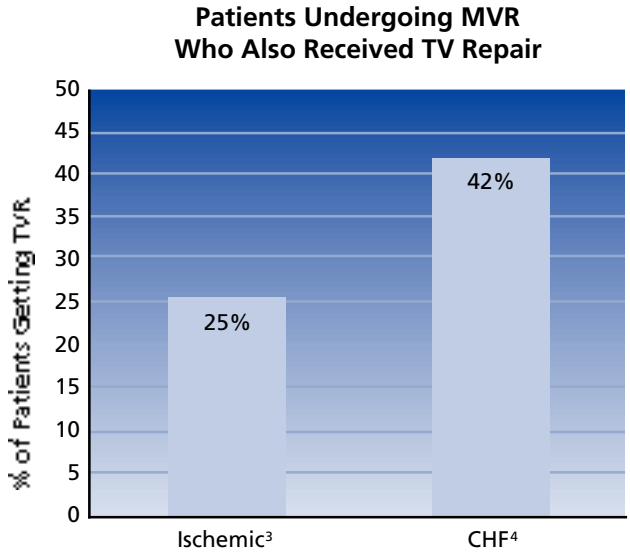
Edwards
LIFESCIENCES

Why Repair the Tricuspid Valve?

"The message then is to be liberal in the indications for tricuspid annuloplasty. The alternative is to accept a number of patients who will need a reoperation for late tricuspid insufficiency with a high mortality and morbidity."[1]

"Remodeling annuloplasty of the tricuspid valve based on tricuspid dilatation improves functional status irrespective of the grade of regurgitation. Considerable tricuspid dilatation can be present even in the absence of substantial TR."[5]

Tricuspid Disease Frequently Accompanies Left-Sided Disease



Etiology of Mitral Valve Disease

- TR does not disappear once the left lesion has been corrected.[5]
- Tricuspid insufficiency may persist or recur despite correction of left-sided lesion.[1]

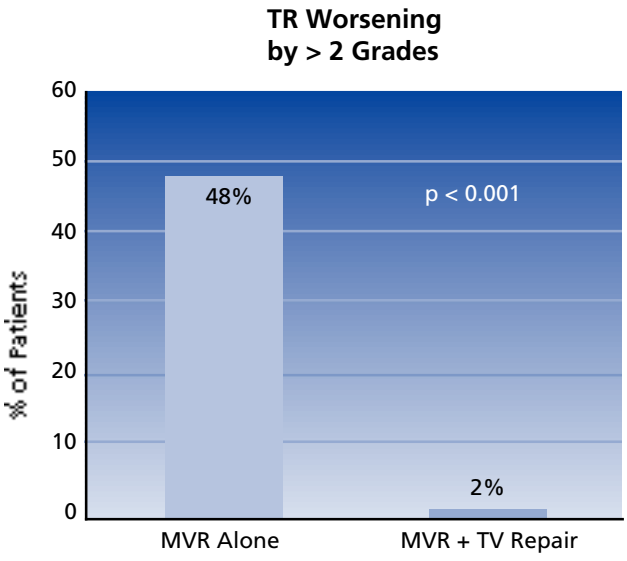
Why Use the Edwards MC³ Ring?

- Increases ease-of-use and operative efficiency.
- Assists in visual orientation of ring placement.
- Stabilizes ring during suturing.
- Does not interfere with tying of sutures and contains a retrieval system during the removal process.

The Edwards MC³ ring conforms to the natural shape of the tricuspid valve

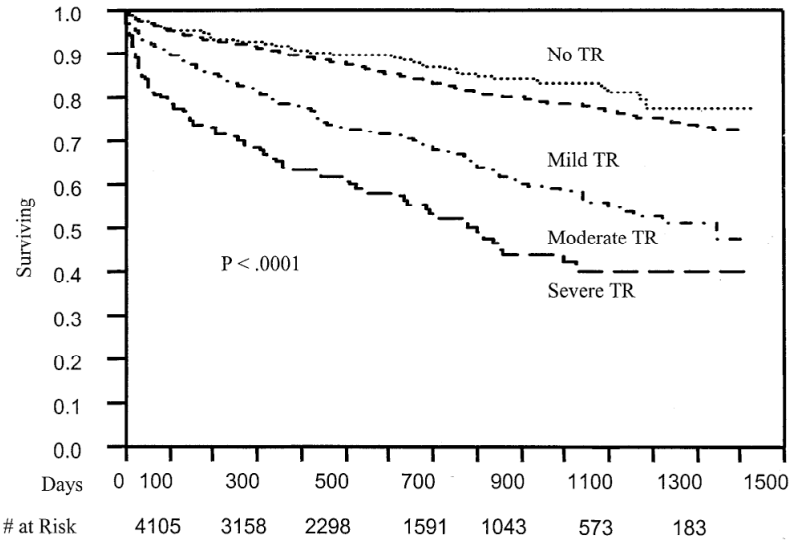
Lanyard system facilitates ease of implantation in a variety of operative settings.

TR is a Progressive Ongoing Process[5]



- Once the annulus is dilated, the progression of TR will subsequently become clinically relevant.[5]
- Having to reoperate for tricuspid valve disease is a high-risk procedure.[6]

Grade of TR Significantly Impacts Survival[7]*

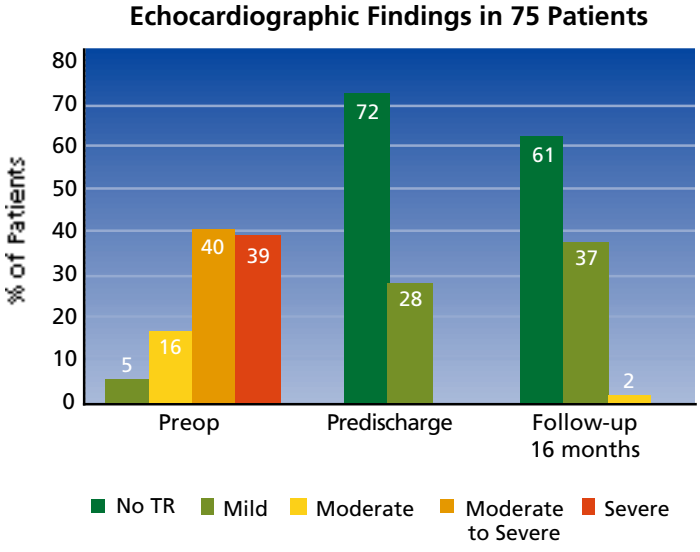


- "Increasing TR severity is associated with worse survival in men regardless of LVEF or pulmonary artery pressure."[7]

The Edwards MC³ Annuloplasty Ring

- Its anatomically correct design conforms to the 3-D tricuspid orifice and minimizes stress on sutures.
- It provides more accurate remodeling.
- Progressive flexibility is created from the unique processing of the titanium band.
- The Edwards MC³ annuloplasty ring is covered with material that encourages host tissue ingrowth.

Edwards MC³ Ring Clinical Findings[8]



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

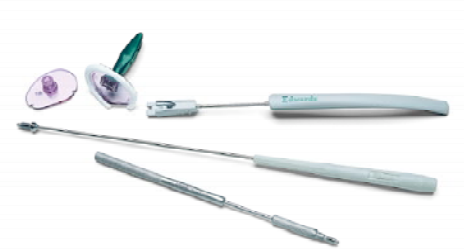
ACC/AHA Guidelines Support Concomitant Tricuspid Repair

"Tricuspid annuloplasty is reasonable for mild TR in patients undergoing MV repair when there is pulmonary hypertension or tricuspid annular dilatation."[2]

"TR associated with dilatation of the tricuspid annulus should be repaired because tricuspid dilatation is an ongoing process that may progress to severe TR if left untreated."[2]

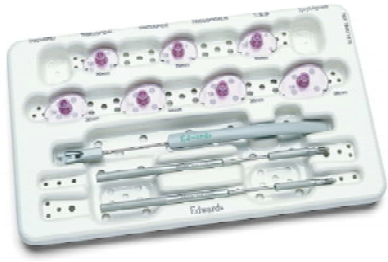
Edwards MC³ Tricuspid Annuloplasty System

The Edwards MC³ Tricuspid Annuloplasty System is constructed of titanium alloy and has a sewing ring that consists of a layer of silicone rubber covered with polyester velour cloth sewn with a single seam. The ring is provided sterile and nonpyrogenic in double-wrapped, clear trays.



Edwards MC³ tricuspid annuloplasty system components

Model Description	Model Number
Edwards MC³ Tricuspid Annuloplasty System (sizes 26 mm - 36 mm)	4900
Tricuspid sizers	1175
Handle	1150
Handle for Sizers (reusable)	1111
Handle for Sizers (single use)	1126



Edwards MC³ tricuspid annuloplasty system accessory tray

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2. Bonow, et al. ACC/AHA 2006 Guidelines for the Management of Patients with Valvular Heart Disease. J Am Coll Cardiol. 2006 Aug 1;48(3):e1-148.
3. Daimon M, et al. Mitral valve repair with Carpentier-McCarthy-Adams IMR ETlogix annuloplasty ring for ischemic mitral regurgitation. Circulation. 2006;114[suppl I]:I-588 – I-593
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7. Nath J, Foster E, Heidenreich P. Impact of tricuspid regurgitation on long-term survival. J Amer Coll Cardiol. 2004;43:405-409.
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Edwards Lifesciences

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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

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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

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

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