Edwards

Carpentier-Edwards Physio II Annuloplasty Ring

Model 5200

For Single Use Only

1.0 Product Description

The Carpentier-Edwards Physio II ring, model 5200, is an annuloplasty ring constructed of cobalt-chromium bands separated by polyester film strips and has a sewing cuff that consists of a layer of silicone rubber covered with a woven polyester cloth. Transverse colored threads indicate the anterior and posterior commissures and the center of the posterior portion of the ring (Figure 2).

The ring exhibits characteristics of selective flexibility with rigidity in the anterior portion and flexibility in the posterior portion. The annular plane of the ring is saddle-shaped.

The design of the ring is intended to provide support after annuloplasty surgery. The ring maintains a fixed maximum annular dimension to prevent excessive distension of the natural valve annulus while adapting to the dynamic motion of the mitral annulus throughout the cardiac cycle.

The ring is provided on a holder to facilitate implantation. The handle, models 1150 and 1151, may be used with the holder to further facilitate implantation. The handles are packaged separately (Figure 3).

2.0 Safety in the Magnetic Resonance (MR) Environment

MR Conditional

Non-clinical testing has demonstrated that the Carpentier-Edwards Physio II ring, model 5200, is MR conditional. A patient with this ring can be scanned safely, immediately after placement of this implant under the following conditions:

- Static magnetic field of 3 Tesla or less
- Maximum spatial magnetic gradient field of 720 gauss/cm
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of scanning (i.e. per pulse sequence)

In non-clinical testing, the ring produced a temperature rise of less than or equal to 1.8 °C at a maximum MR system whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg as assessed by calorimetry for 15 minutes of MR scanning in a 3 Tesla MR system (Excite, General Electric Healthcare, Software G3.0-052B).

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Optimization of MR imaging parameters is recommended.

3.0 Mitral Valve Reconstruction Techniques

For specific techniques on mitral valve reconstruction, see the clinical literature referenced in Section 14.0 "References".

4.0 Indications

The Carpentier-Edwards Physio II ring, model 5200, is intended for the correction of mitral valve insufficiency, or mixed mitral insufficiency and stenosis, where treatment does not necessitate a replacement of the natural mitral valve.

5.0 Contraindications

1. Severe organic lesions with retracted chordae
2. Congenital malformations with lack of valvular tissue
3. Large valvular calcifications
4. Active bacterial endocarditis
5. In children where future growth may compromise the effective valve area

6.0 Warnings

6.1 For Single Use Only

This device is designed, intended, and distributed for SINGLE USE ONLY. DO NOT RE-STERILIZE OR REUSE THIS DEVICE. There are no data to support the sterility, non-pyrogenicity and functionality of the device after reprocessing. Such action could lead to illness or an adverse event as the device may not function as originally intended.

As with any implanted device, there is potential for an immunological response.

Do not cut any threads on the ring. Cutting these threads can create loose threads with the potential for thromboembolism or hemolysis.

Surgeons who use annuloplasty rings should be current on all anticoagulation regimes.

Hemolysis due to regurgitation is a potential risk. Hemolysis may occur even with mild regurgitation.

Heart block and damage to coronary arteries are potential risks.

Patients with annuloplasty rings or bands who undergo dental or other potentially bacteremic procedures must be considered for prophylactic antibiotic therapy.

Do not attempt to deform or alter the ring to conform to a specific annular anatomy, as it could damage the ring. If the ring is not suitably sized for the annulus, select a larger or smaller ring. For more information, refer to section 9.1 "Measurement and Selection of the Appropriate Ring."

Remove the holder from the ring after the ring is implanted. Implantation of the holder with the ring can cause patient injury or death. In the event that a holder needs to be located within the surgical site, a radiopaque component within the holder can be detected under x-ray.

This device was manufactured without latex but may have been produced in a latex-containing environment.

Components of the Model 5200 include polyester, silicone, and a metal alloy containing cobalt, chromium, nickel, molybdenum, manganese, carbon, beryllium, and iron. Care should be exercised in patients with hypersensitivities to these materials. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/ hypersensitivity to these materials.

7.0 Precautions

A serial number tag is attached to the ring by a suture. Do not detach this tag until implant is certain and sizing is completed. During removal of the tag, avoid cutting or tearing the cloth.

Suture needles with sharp cutting edges or forceps with teeth must not be used during insertion to avoid damage to the fabric covering the ring.

Sutures should be placed through the Carpentier-Edwards Physio II ring as demonstrated in Figure 8. Do not place sutures in the atrial tissue, as impairment of cardiac conduction may occur. Avoid suture placement that may injure or compromise the coronary arteries. See "Suture Placement" for more information.

Inspect the packaging, ensuring that it has not been opened or damaged. Do not use rings that have been removed from the double trays and dropped, soiled, or possibly damaged.

Gentle handling is required for all implantable rings. To ensure the sterility and integrity of the ring, the ring should be stored in the product box until implantation is imminent.

Sizing the annulus properly is essential. Use only the appropriate sizers provided by Edwards Lifesciences LLC to size the ring and the annulus. Do not attempt to use ring holder as a sizer. For more information, refer to Section 9.1 "Measurement and Selection of the Appropriate Ring."

Do not use the ring after the expiration date on the label.

8.0 Complications

A full explanation of the benefits and risks must be given to each prospective patient before surgery.

Serious complications, sometimes leading to death, have been associated with the use of rings. In addition, complications due to individual patient reaction to an implanted device, or to physical or chemical changes in the components, may necessitate reoperation and replacement (sometimes within weeks or months) of the prosthetic device.

Careful and continuous medical follow-up (per the surgeon's standard of care routine) is advised so that prosthesis-related complications can be diagnosed and properly managed to minimize risk to the patient.

Uncorrected or recurrent mitral regurgitation is a potential complication associated with annuloplasty rings.

Following is a list of complications associated with mitral valve repair and prosthetic ring annuloplasty compiled from literature and from reports received through the Edwards complaint handling system.

Procedural and Product Complications:

- residual or recurrent mitral regurgitation;
- stenosis;
- thrombosis;
- thromboembolism;
- hemolysis;
- heart block;
- low cardiac output, right heart failure;
- recurrence of mitral regurgitation due to progression of natural degenerative disease, endocarditis, or inadequate/incomplete repair of the valvular and subvalvular structures;
- damage to coronary arteries;
- complications related to prolonged bypass, aortic cross clamping and inadequate myocardial protection;
- tearing of the cloth covering with the use of cutting needles;
- bleeding related to the use of anticoagulation therapy;
- local and/or systemic infection;
- dislodgement of the ring from its site of attachment (dehiscence);
- malfunction of the ring due to distortion at implant or physical or chemical deterioration of ring components;
- fracture of the ring components;
- fraying of the cloth or suture material;
- systolic anterior motion (S.A.M.) and left ventricular outflow tract obstruction (L.V.O.T.O.) whenever a large posterior or anterior leaflet is present;
- endocarditis;
- atrio-ventricular disruption or rupture;
- allergic reactions;
- fibrous tissue overgrowth or pannus;
- suture breakage upon incorrect placement of sutures into the ring

9.0 Instructions for Use

9.1 Measurement and Selection of the Appropriate Ring

Ring selection is based on measurements of the inter-commissural distance and the height and/or surface area of the anterior leaflet using the Edwards model 1152 or

1252 mitral sizers. Figure 4 demonstrates a measurement of the inter-commissural distance of the mitral valve with the sizer. Figure 5 shows a measurement of the anterior leaflet height and surface area after the anterior leaflet has been unfurled (Refs. 8-9).

Various sizers should be tried to select the optimal size of Carpentier-Edwards Physio II ring. The size that corresponds to the intercommissural distance (between the two notches on the sizer) and the height of the anterior leaflet is the one that should be selected. The free edge of the anterior leaflet must not extend more than 1 mm beyond the inferior edge of the sizer (Ref. 1).

In patients with functional mitral regurgitation, a downsizing approach may be considered. Recent cardiology guidelines suggest this may offer a benefit to patients with this type of valvular dysfunction (Refs. 10-11). Surgical centers have published results using a downsized remodeling annuloplasty ring in patients with functional mitral regurgitation (Refs. 12-13).

If the surgeon is deciding between two sizes in patients with degenerative valve disease, the selection of the greater size is recommended in most instances. In Barlow's disease, the typical size of the ring is between 36 mm and 40 mm. The choice of too small a ring increases the risk of post-repair systolic anterior motion (SAM) (Ref. 2).

CAUTION: Examine sizers and handles for signs of wear, such as dullness, cracking or crazing. Replace sizer/handle if any deterioration is observed.

WARNING: Non-metal fragments of holders, handles, and sizers are not radiopaque and may not be detected by means of an external imaging device.

9.2 Use of Handle and Holder

Insertion of the Carpentier-Edwards Physio II ring may be accomplished using the holder and optional handles (model 1150 or 1151, which are packaged separately). The holder on the ring is designed with windows which allows visualization of the mitral valve during parachuting. In addition, the holder is angled toward the anterior portion of the ring to further assist with visualization.

Attach the optional handle to the holder in a one-step motion by snapping the handle into the engaging component on the holder. See Figure 6. To bend the handle, grip the ends and gently apply force to bend the stainless steel shaft. Bent angles should be limited to 45° in an up and down direction for a maximum of 30 times for the life of the device. After the holder is removed from the ring, the handle can be removed from the holder by gripping the holder at the connection point and pulling the handle off. See Figure 7. Discard the holder.

The handle is reusable. For more information, refer to section 11.3 "Cleaning and Sterilization Instructions."

Handles should be examined for signs of wear, such as dullness, cracking, or crazing and should be replaced immediately if any deterioration is observed.

Accessories should be replaced on a routine basis. Contact your Edwards Lifesciences sales representative to obtain appropriate replacements.

The annuloplasty ring must be removed from the holder after the ring is implanted. Implantation of the holder can cause patient injury or death. In the event that a holder needs to be located within the surgical site, a radiopaque pin within the holder can be detected under x-ray.

9.3 Insertion of the Ring

The annuloplasty is performed by first placing horizontal mattress sutures circumferentially through the annulus 1 to 2 mm outside the junction between the leaflet and the atrium. Suture placement is facilitated by firmly grasping the body of the leaflet tissue with tissue forceps (Refs. 8-9).

9.4 Suture Placement on the Ring

The Carpentier-Edwards Physio II ring is designed with a sewing cuff for ease of suture placement. The cuff design is depicted in Figure 9.

In addition, the sewing cuff is delineated by a green circular outflow mark to further assist with suture placement.

Annular sutures are spaced equally in the area between the two commissures and the corresponding segment of the ring. In the remaining portion of the annulus, the spacing is set to conform the annulus to the shape and size of the ring (Ref. 8). Approximately 12-16 sutures are needed. Refer to Figure 8.

To ensure proper placement of the sutures on the ring and to prevent contact with the cobalt-chromium bands of the ring, the following technique is to be used:

Step	Procedure
1	Interrupted horizontal sutures should be placed in the Carpentier-Edwards Physio II ring as demonstrated in Figure 9.
2	If resistance is met when the suture needle is passed through the ring, pull the suture needle out of the ring and begin again by placing the suture through the sewing cuff as demonstrated in Figure 9.

9.5 Removal of the Ring Holder

The Carpentier-Edwards Physio II ring is designed with a single-cut holder release. A single suture well is located in the middle of the posterior section of the ring. Caution should be taken not to cut any threads along the anterior portion of the ring. Cutting these threads can create loose threads with the potential for thromboembolism. The thread in the raised area is cut with a scalpel (Figure 10). This facilitates removal of the ring from the holder. The retaining suture is permanently connected to the holder and upon withdrawal of the holder, all retaining sutures are removed. After the holder is detached from the ring, the holder is to be discarded.

Figure 11 illustrates the appearance of the properly implanted annuloplasty ring.

9.6 Evaluating Repair Competency

The quality of the repair should first be evaluated after tying the sutures to the ring. Saline is injected into the ventricle through the mitral valve to observe the line of coaptation. There should be a symmetrical line that is parallel to the posterior portion of the ring with a ¾ to ¼ ratio of anterior leaflet to posterior leaflet within the

orifice. If the line of coaptation is asymmetrical, this suggests a residual leaflet prolapse or restricted leaflet motion; this should be corrected.

Also, if the posterior leaflet occupies more than half or more of the ring orifice area, it should be shortened to mitigate the risk of systolic anterior motion (SAM) (Ref. 8).

The quality of the repair is assessed by transesophageal echocardiography (TEE) after completion of cardiopulmonary bypass. This examination should rule out the presence of postvalvuloplasty SAM in patients with excess leaflet tissue (Ref. 2).

If careful application of the ring method of valvuloplasty fails to produce adequate repair of valvular insufficiency as determined by visual inspection or intraoperative testing, the surgeon should consider alternative treatment options.

10.0 Annuloplasty Ring

10.1 Specifications

Carpentier-Edwards Physio II ring Model 5200

Sizes: 24 mm, 26 mm, 28 mm, 30 mm, 32 mm, 34 mm, 36 mm, 38 mm, 40 mm

10.2 How Supplied

The Carpentier-Edwards Physio II ring with attached holder is provided sterile and nonpyrogenic in a box containing double plastic trays to facilitate handling and transfer to the sterile field at the time of surgery. After opening the outer tray, the inner tray may be placed directly into the sterile field.

10.3 Storage

To minimize contamination and to provide maximum protection, the annuloplasty ring (in double trays), the Instructions for Use, and the Implantation Data Card should be stored inside the outer cardboard box in a clean, dry area until needed. The annuloplasty device cannot be used after the expiration date on the label.

11.0 Accessories

11.1 Specifications

Optional Handles Model 1150 and model 1151

Sizers

Mitral Sizers model 1152 or 1252

Sizes: 24 - 40

Sizer Handle model 1111, 1117 and 1126 (single use)

Sizer/Handle Tray - Mitral model TRAY1152 or TRAY1252

11.2 How Supplied

The accessories are packaged separately, provided nonsterile and must be cleaned and sterilized before each use. They cannot be sterilized in their original packaging.

11.3 Cleaning and Sterilization Instructions

For cleaning and sterilization of listed accessory models refer to the Instructions for Use provided with the Accessories.

12.0 Case History

12.1 Implant Patient Registry

When using an Edwards annuloplasty ring, carefully complete the Implantation Data Card that is packaged with each device. Return the preaddressed portion of the card to the Implant Patient Registry. The remaining portions of the card are provided for hospital and surgeon records. Upon receipt, a wallet-sized identification card will be produced for the patient. The card allows patients to inform healthcare providers what type of implant they have when they seek care. When a ring is discarded or a previous Edwards device is replaced, the Implantation Data Card should be used to report this information to our Registry.

12.2 Recovered Clinical Implants

Edwards Lifesciences LLC, is extremely interested in obtaining recovered clinical specimens of Carpentier-Edwards Physio II rings for analysis. Please contact your local company representative for return of recovered rings. The rings should be placed in a suitable histological fixative such as 10% formalin or 2% glutaraldehyde. Refrigeration is not necessary.

13.0 Physician Training

The techniques for implanting this ring are similar to those used for the placement of any annuloplasty ring. No additional training is required to implant the Physio II annuloplasty ring, model 5200. It is the surgeon's decision when and if to repair a mitral valve.

14.0 References

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2. Filsoufi F, Carpentier A. Principles of Reconstructive Surgery in Degenerative Mitral Valve Repair. *Semin Thorac Cardiovasc Surg* 2007;19:103-110.
3. Braunberger E, et al. Very Long-Term Results (More Than 20 Years) of Valve Repair with Carpentier's Techniques in Nonrheumatic Mitral Valve Insufficiency. *Circulation* 2001;104[suppl I]:I-8-I-11.
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6. Gillinov MA, et al. Is Repair Preferable to Replacement for Ischemic Mitral Regurgitation? *J Thorac Cardiovasc Surg* 2001;122:1125-41.
7. Accola KD, et al. Midterm Outcomes Using the Physio Ring in Mitral Valve Reconstruction: Experience in 492 Patients. *Ann Thorac Surg* 2005;79:1276-83.
8. Mitral Valve Repair at the Mount Sinai Hospital, www.mitralvalverepair.org.
9. Carpentier A. Cardiac Valve Surgery: The French Correction. *J Thorac Cardiovasc Surg* 1983;86:323-337.
10. Bonow et al. ACC/AHA Guidelines for the Management of Patients with Valvular Heart Disease. *J Am Coll Cardiol* 2006;48(3):63-107.

11. Vahanian et al. European Society of Cardiology Guidelines on the Management of Valvular Heart Disease. *Eur H Journal* 2007;28:230-268.

12. Braun et al. Restrictive Mitral Annuloplasty Cures Ischemic Mitral Regurgitation and Heart Failure. *Ann Thorac Surg* 2008;85:430-7.

13. Gazoni LM, et al. A Change in Perspective: Results for Ischemic Mitral Valve Repair Are Similar to Mitral Valve Repair for Degenerative Disease. *Ann Thorac Surg* 2007;84:750-758.

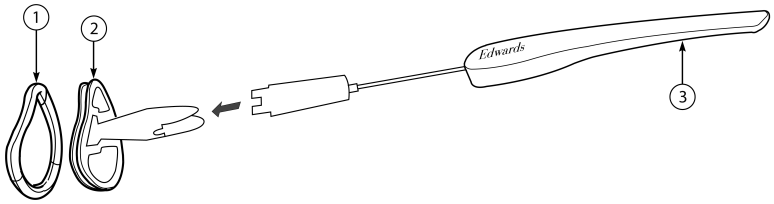
14. Meurin P, et al. Thromboembolic Events Early after Mitral Valve Repair. *Int J Cardiol* 2008;126:45-52.

15. Carpentier A., Adams D.A., Filsoufi F. Carpentier's Reconstructive Valve Surgery. Maryland Heights, MO: Saunders Elsevier, 2010.

16. Guidelines on the management of valvular heart disease (version 2012). The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

17. 2017 AHA/ACC Focused update of the 2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease

Figures



1. Ring
2. Holder
3. Handle

Figure 1

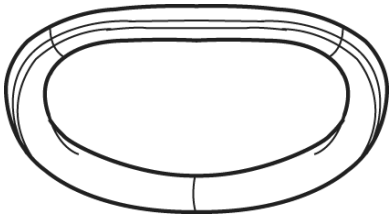


Figure 2

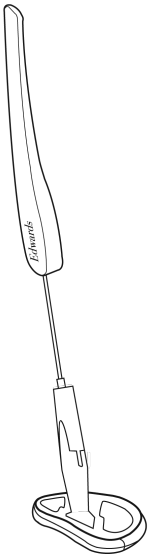


Figure 3

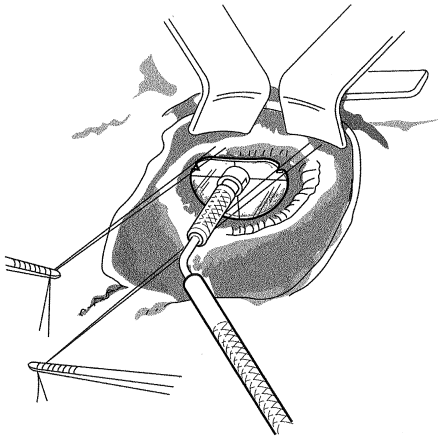


Figure 4

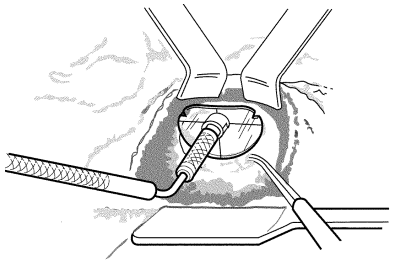


Figure 5

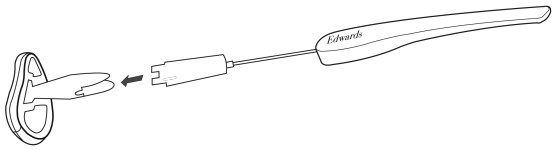


Figure 6

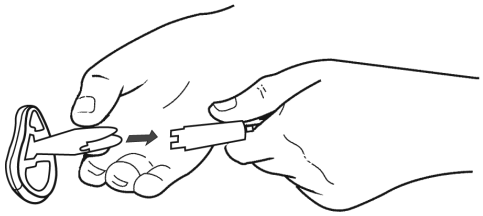


Figure 7

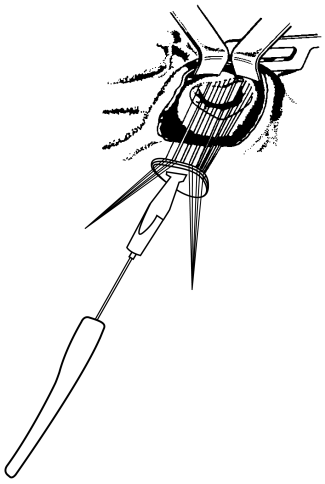
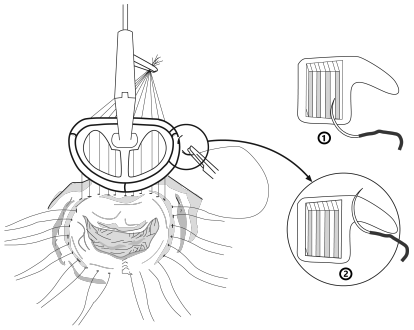


Figure 8



1. Incorrect
2. Correct

Figure 9

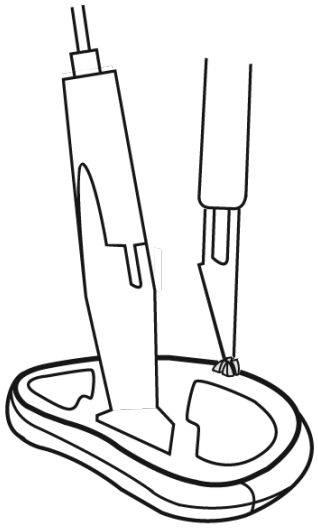


Figure 10

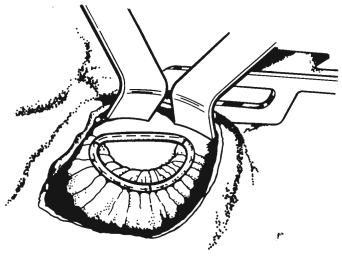


Figure 11

Symbol Legend

	English
	Catalogue Number
	Caution
	Consult instructions for use
	Consult instructions for use on the website
	Do not re-use
	Do not resterilize
	Quantity

	English
	Use-by date
	Serial Number
	Conformité Européenne (CE Mark)
	Manufacturer
	Date of manufacture
	MR Conditional

	English
	Non-pyrogenic
	Do not use if package is damaged
	Sterilized using steam or dry heat
	Authorized representative in the European Community
	Store in a cool, dry place
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

EC REP

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