



Edwards

Carpentier-Edwards Physio Annuloplasty Ring Mitral with Holder

Model 4450

For Single Use Only

1.0 Product Description

The Carpentier-Edwards Physio annuloplasty ring, Model 4450 is constructed of Elgiloy bands separated by polyester film strips and has a sewing ring margin that consists of a layer of silicone rubber covered with a woven polyester cloth.

The mitral annuloplasty ring conforms to the configuration of a normal mitral annulus. It is kidney-shaped with one long curved segment corresponding to the posterior leaflet annulus. A rectilinear portion corresponds to the anterior leaflet annulus. Transverse colored threads indicate the anterior and posterior commissures (Figure 2).

The ring exhibits characteristics of differential flexibility. While retaining stiffness, the annuloplasty ring is also flexible in the portion corresponding to the anterior leaflet. The flexibility is increased in the posterior regions of the ring. Along the annular plane the ring is stable with a saddle-shaped curve for apposition to the aortic root.

Transverse colored thread facilitates location of the commissures and proper positioning of the ring.

The holder, designed to facilitate ring implantation, is manufactured from an amorphous polymer. The annuloplasty ring is mounted on the holder with three retaining sutures (Figure 3).

The handle, Model 1150, may be utilized in conjunction with the holder to facilitate ease of suture placement and implantation. The middle section of the handle is malleable, allowing the handle to be adjusted (bent) in a configuration convenient for use. The handle is packaged separately. The snap assembly of the handle and holder allows for connecting and disconnecting the two components at appropriate times during the surgical procedure.

2.0 Safety in the Magnetic Resonance (MR) Environment



MR Conditional

Non-clinical testing has demonstrated that the Carpentier-Edwards Physio annuloplasty ring (model 4450), is MR Conditional. A patient with the Carpentier-Edwards Physio annuloplasty 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 gradient field of 720 gauss/cm or less

- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning (i.e. per pulse sequence)

In non-clinical testing, Carpentier-Edwards Physio annuloplasty ring (model 4450), produced a temperature rise of less than or equal to 0.6 °C at a maximum whole-body-averaged specific absorption rate (SAR) of 3 W/kg 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 Indications

The Carpentier-Edwards Physio annuloplasty ring 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.

4.0 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

5.0 Warnings

5.1 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.

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

Patients with annuloplasty rings 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.

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

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.

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

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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 4450 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.

6.0 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.

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.

For ease of orientation, the sewing ring is marked with a colored thread (Figure 2). **The side of the ring with the colored thread around the circumference always lies against the valve annulus.**

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.

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

7.0 Complications

A full explanation of the benefits and risks should 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

8.0 Instructions for Use

8.1 Measurement and Selection of the Appropriate Ring

Because the technique is intended to restore a physiological orifice, measurement and ring selection is based on the measurement of the anterior leaflet attachment by using sizers.

The sizers present two marks on their linear segment (Figure 4). The delineation of the anterior leaflet attachment may be difficult in some cases; therefore, the ring may also be selected by measuring the surface of the anterior leaflet with the same sizers (Figure 5).

To facilitate this measurement, the chordae tendineae may be placed on tension, thus spreading the leaflet. The annuloplasty ring is selected whose surface area most closely corresponds to the surface area of the anterior leaflet.

In rare cases, when a portion of the anterior leaflet protrudes beyond the obturator, the following technique should be used:

Step	Procedure
1	Choose a sizer one size greater than utilized for the previous measurement.
2	If this sizer covers the anterior leaflet protrusion, check to ensure that the commissural markers on the obturator correspond to the commissures of the annulus. If the sizer corresponds to the commissures and covers the full anterior leaflet, the larger size ring should be chosen.
3	In those cases where the larger sizer causes the commissural markers on the obturator to extend beyond the commissures of the annulus, the smaller size ring should be chosen and the anterior leaflet protrusion should be reduced so that the anterior leaflet surface area corresponds to the sizer.

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.

8.2 Use of Handle and Holder

Insertion of the mitral prosthesis may be accomplished with the handle and holder, with the holder alone, or without either holder or handle.

If using the handle and holder, attach the handle to the holder in a one-step motion by snapping the handle into an engaging component on the holder (see Figure 6). It is recommended that the holder and handle be removed during the insertion procedure just prior to tying off the sutures. After the holder is detached from the ring (see **Removal of the Holder**), disconnect handle from holder by gripping the holder at the connection point while pulling the handle off (see Figure 7). Discard the holder. The handle is reusable.

If using the holder without the handle, remove the ring from the holder just prior to tying off the sutures (see **Removal of the Holder**). After the holder is detached from the ring, discard the holder.

If using neither the handle nor the holder, detach the annuloplasty ring from the holder prior to insertion of the ring (see **Removal of the Holder**). After the holder is detached from the ring, discard the holder.

The annuloplasty ring must be removed from the holder prior to implantation. Implantation of the holder can cause patient injury or death. In the event that a holder needs to be located within the surgical site, its presence can be detected under x-ray.

8.3 Insertion of the Mitral Prosthesis

Insertion of the mitral prosthesis can be done by interrupted horizontal sutures in the fibrous mitral annulus 2 mm from the leaflet hinge. Approximately 10 to 12 sutures are needed.

To facilitate exposure of the mitral annulus for passing the suture, the leaflet should be tensed with forceps.

A precise relationship between leaflet and corresponding segments of the annuloplasty ring should be maintained.

Note: The side of the ring with the colored thread around the circumference always lies against the annulus.

8.4 Suture Placement

To ensure proper placement of the sutures on the ring and prevent hitting the internal polyester film or Elgiloy strips of the ring, which may potentially fray the suture material, the following technique is to be used:

Step	Procedure
1	The interrupted horizontal sutures should be placed in the annuloplasty ring no more than 1.5 mm from the outer ring of the sewing ring (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 needle within 1.5 mm of the outer ring of the ring. Resistance occurs when the suture material is in direct contact with the polyester film or Elgiloy strips. Pulling on the suture at this time may fray the suture material, thus creating the potential for suture breakage.

8.5 Removal of the Holder

The annuloplasty ring is removed from the holder by cutting three retaining sutures. Three raised areas with slots are provided

to permit the surgeon to cut the retaining sutures with a scalpel (Figure 10). This facilitates rapid removal of the annuloplasty ring from the holder. The retaining sutures are permanently connected to the holder and upon withdrawal of the holder, all retaining sutures are removed. After the holder is detached from the annuloplasty ring, the holder is to be discarded.

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

8.6 Testing

Valvular competency is tested by injecting saline into the left ventricle through the mitral orifice, after the aortic root has been vented to prevent air embolism into the coronary arteries.

Repair is judged to be satisfactory if the line of leaflet closure is parallel to the mural part of the ring; this indicates a good apposition of the leaflet. Intraoperative echo has been instrumental in assessing valvular competency and the quality of repair.

Care in the measurement of the orifice, ring selection, and insertion are essential in achieving a good result. However, associated subvalvular lesions necessitate additional procedures.

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.

9.0 Annuloplasty Ring

Specifications

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

9.1 How Supplied

The Carpentier-Edwards Physio annuloplasty 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.

9.2 Storage

To minimize contamination and to provide maximum protection, the annuloplasty band/template (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. Stock rotation at required intervals is recommended to ensure usage of the annuloplasty device by the date stamped on the label. The annuloplasty device cannot be used after the date stamped on the label.

10.0 Accessories

Specifications

Optional Handle Model 1150

Sizers/Handles (Push Fit Connection)

Push Fit **Mitral** Sizers Model 1164

Sizes: **M24–M40**

Push Fit Sizer Handle Model 1146

Sizers/Handles (Threaded Connection)

Threaded **Mitral** Sizers Model 1174

Sizes: **M24–M40**

Threaded Sizer Handle Model 1111

Sizer/Handle Tray – Mitral Model TRAY1174

Note: Corresponding sizers are necessary to aid in the selection of the appropriate annuloplasty device size during surgery.

10.1 How Supplied

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

Sizers corresponding to the various sizes of annuloplasty devices are available (see **Specifications**). These sizers should be used at the time of operation for accurate selection of the appropriate size annuloplasty device for the patient.

10.2 Cleaning and Sterilization Instructions

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

11.0 Case History

11.1 Implant Patient Registry

When an Edwards prosthetic annuloplasty ring is used, carefully complete the Implantation Data Card that is packaged with each device. Return the preaddressed portion of the card to our Implant Patient Registry. The remaining portions of the card are provided for hospital and surgeon records. Upon receipt by our Registry, a wallet-sized identification card will be produced for the patient. This 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.

11.2 Recovered Clinical Implants

Edwards Lifesciences Corporation, is extremely interested in obtaining recovered clinical specimens of Carpentier-Edwards Physio annuloplasty 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.

12.0 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 annuloplasty ring, model 4450. It is the surgeon's decision when and if to repair a mitral valve.

13.0 References

1. Carpentier A., Adams D. A., Filsoufi F. Carpentier's Reconstructive Valve Surgery. Maryland Heights, MO: Saunders Elsevier, 2010.
2. 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)
3. 2017 AHA/ACC Focused update of the 2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease

Figures

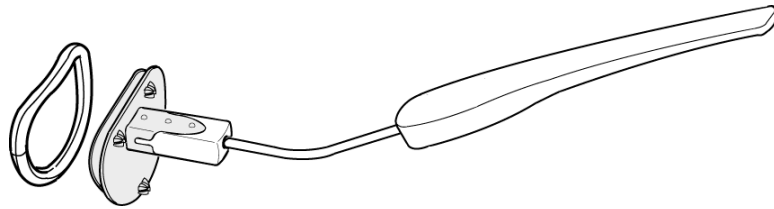


Figure 1: Use of holder and ring handle is optional

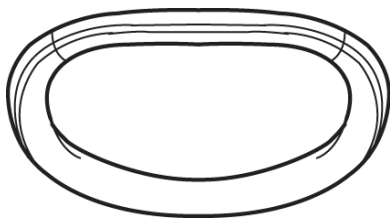


Figure 2

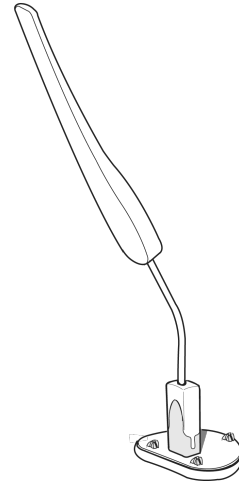


Figure 3

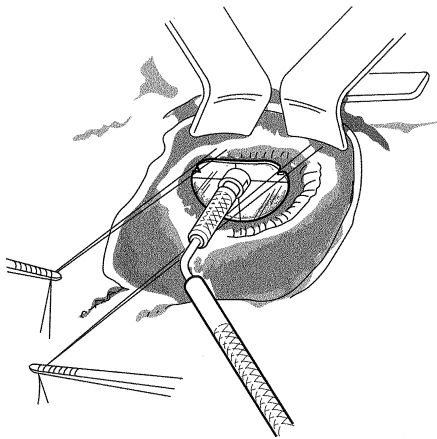


Figure 4

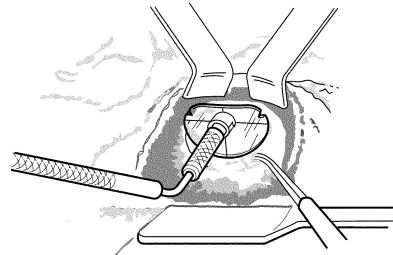


Figure 5

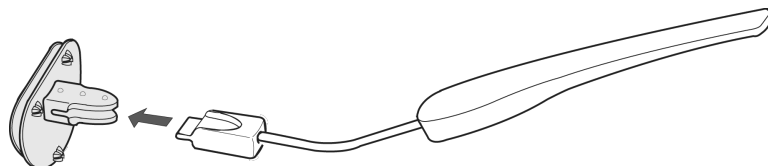


Figure 6

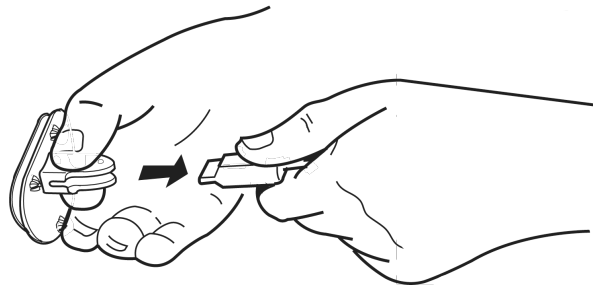


Figure 7

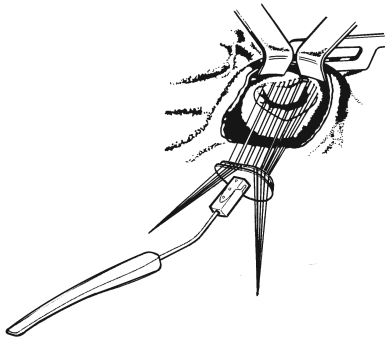
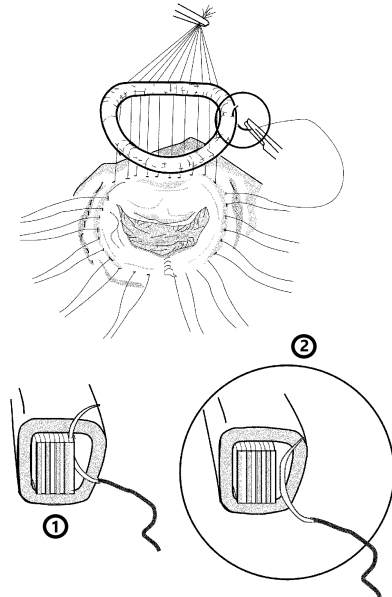


Figure 8



- 1. Incorrect
- 2. Correct

Figure 9

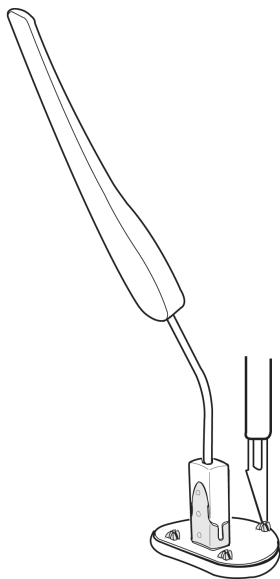


Figure 10

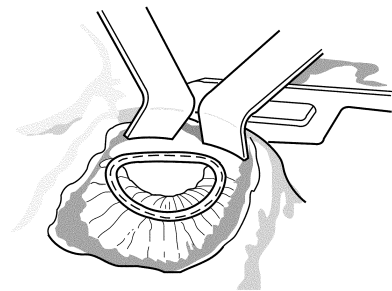

















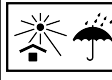



Figure 11

Symbol Legend

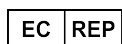
	English
	Catalogue Number
	Caution
	Consult instructions for use
	Consult instructions for use on the website
	Do not re-use
	Do not re-sterilize
	Quantity

	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
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.



Edwards



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05/22
10052675001 A / DOC-0198260 A
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