Edwards

Carpentier-Edwards Physio Tricuspid Annuloplasty Ring

Model 6200

For Single Use Only

1.0 Product Description

The Carpentier-Edwards Physio Tricuspid annuloplasty ring, model 6200, is designed to maintain support of the tricuspid annulus to prevent excessive dilatation, while adapting to the dynamic motion of the tricuspid annulus in the direction of flow during the cardiac cycle.

The ring is constructed of a titanium core. The ring's sewing cuff consists of silicone rubber that is covered with a woven polyester cloth and polyethylenetetrafluoroethylene thread. Transverse colored polyethylene-terephthalate thread markings on the ring indicate the anteroposterior and the posteroseptal commissures (Figure 2), and a dashed line of colored polyethylene-terephthalate thread indicates the edge of the sewing cuff and the outflow side of the ring.

The ring has a waveform contour with selective flexibility of the different segments designed to adapt to the complex motion of the annulus. The anteroseptal commissure is open to avoid the conduction system.

The ring is provided on a holder to facilitate implantation. The holder is designed with windows that allow visualization of the tricuspid valve during parachuting. In addition, the holder is angled toward the anterior portion of the ring to further assist with visualization.

2.0 Indications

The Carpentier-Edwards Physio Tricuspid annuloplasty ring, model 6200, is intended for use in patients with tricuspid insufficiency, to correct annular dilatation, increase leaflet coaptation, reinforce annular suture lines, and prevent further dilatation of the annulus.

3.0 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

4.0 Warnings

4.1 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.

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.

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.

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.

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

Components of the Model 6200 include polyester, silicone, and a metal alloy containing titanium, vanadium, and aluminum. 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.

5.0 Precautions

Examine sizers for signs of wear, such as dullness, cracking or crazing. If you observe any deterioration, replace the sizers immediately.

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.

Examine handle for signs of wear, such as dullness, cracking or crazing. If you observe any deterioration, replace the handles immediately.

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 use the ring after the expiration date on the label.

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.

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.

6.0 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 tricuspid regurgitation is a potential complication associated with annuloplasty rings.

Following is a list of complications associated with tricuspid 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 tricuspid regurgitation;
- stenosis;
- thrombosis;
- thromboembolism;
- hemolysis;
- heart block;
- low cardiac output, right heart failure;
- recurrence of tricuspid 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;
- endocarditis;
- atrio-ventricular disruption or rupture;
- allergic reactions;
- fibrous tissue overgrowth or pannus.

7.0 Instructions for Use

7.1 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 Tricuspid annuloplasty ring, model 6200. It is the surgeon's decision when and if to repair a tricuspid valve.

7.2 Measurement and Selection of the Appropriate Ring

Use model 1262 sizers to measure the tricuspid valve for annuloplasty ring size. Typical sizing technique for tricuspid valve annuloplasty includes assessment of septal leaflet length using the two notches on the 1262 sizer (Figure 4), and evaluation of anterior leaflet surface area (Figure 5).

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

WARNING: 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.

7.3 Use of Handle and Holder

The Carpentier-Edwards Physio Tricuspid ring may be inserted using the holder and optional handle model 1150 or 1151, which are packaged separately (Figure 6).

Attach the optional handle to the holder in a one-step motion by snapping the handle into the engaging component on the holder (Figure 6).

To bend the handle, grip the ends and gently apply force to bend the stainless steel shaft (Figure 3).

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

7.4 Ring Implantation

The Carpentier-Edwards Physio Tricuspid ring is designed with a sewing cuff for ease of suture placement (Figure 7).

The sewing cuff is delineated by a green circular outflow mark to further assist with suture placement.

Once you have selected the ring, place a series of horizontal mattress sutures at equidistant points around the tricuspid annulus.

CAUTION: 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.

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

CAUTION: 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.

The transverse colored thread markings on the ring help orientate the ring to the anteroposterior and the posteroseptal commissures (see Figure 2). Pass the sutures through the green outflow marks in the sewing cuff (Figure 7) of the selected ring.

Remove the serial number tag and parachute the ring.

7.5 Removal of the Ring Holder

The Carpentier-Edwards Physio Tricuspid ring is designed with a single-cut holder release. A single suture well (Figure 8) is located in the posterior section of the ring.

Cut the retaining suture thread in the raised area with a scalpel (Figure 8). This facilitates removal of the ring from the holder.

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

Pull the holder. The retaining suture is permanently connected to the holder and upon withdrawal of the holder the retaining suture is removed (Figure 8).

WARNING: 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.

Remove the handle from the holder by gripping the holder at the connection point and pulling the handle off. Discard the holder. The handle is reusable. For more information refer to Section 10.2 "Cleaning and Sterilization Instructions."

Figure 9 illustrates a properly implanted annuloplasty ring.

7.6 Evaluating Repair Competency

Assess the quality of the repair by transesophageal echocardiography (TEE) after completion of cardiopulmonary bypass. Care in the measurement of the orifice, annuloplasty ring selection, and insertion technique are essential in achieving a good result. However, associated subvalvular lesions may necessitate additional procedures.

If careful application of the annuloplasty ring fails to produce adequate repair of valvular insufficiency as determined by echocardiography, visual inspection, or intraoperative testing, be prepared to consider alternative treatment options.

8.0 Safety in the Magnetic Resonance (MR) Environment

MR Conditional

Non-clinical testing demonstrated that the Carpentier-Edwards Physio Tricuspid annuloplasty ring, model 6200, is MR conditional. A patient with this ring can be safely scanned immediately after placement of this implant, under the following conditions:

- Static magnetic field of 3 tesla or less
- Maximum spatial magnetic gradient field of 2500 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 2.4 °C at a maximum whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of MR scanning in a 3 tesla MR system (Signa HDX, General Electric Healthcare, Software 14\LX \MR).

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.

9.0 Annuloplasty Ring

9.1 Specifications

The Carpentier-Edwards Physio Tricuspid ring is offered in the following sizes:

24 mm, 26 mm, 28 mm, 30 mm, 32 mm, 34 mm, and 36 mm.

9.2 How Supplied

The Carpentier-Edwards Physio Tricuspid 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.

9.3 Storage

To minimize contamination and to provide maximum protection, store the annuloplasty ring (in double trays), Instructions for Use, and Implantation Data Card contained inside the outer cardboard box in a clean, dry area until needed.

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

CAUTION: 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.

10.0 Accessories

Sizers: Tricuspid Sizers model 1262, Sizes: 24 – 36

Sizer/Handle Tray: Tricuspid model TRAY1262

Optional Holder Handles: model 1150 and model 1151

10.1 How Supplied

Accessories are packaged separately, provided non-sterile and must be cleaned and sterilized before each use. Do not sterilize accessories in their original packaging.

Replace accessories on a routine basis. Contact your Edwards Lifesciences sales representative to obtain appropriate replacements.

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 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, and keep the remaining portions for hospital and surgeon records. Upon receipt of the Implantation Data Card, the Implant Patient Registry will produce a wallet-sized identification card 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, use the Implantation Data Card to report this information to our Registry.

11.2 Recovered Clinical Implants

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

12.0 References

1. Carpentier, A et al. *Carpentier's Reconstructive Valve Surgery*. Missouri: Saunders Elsvier, 2010.
2. Navia, et al. Surgical Management of Secondary Tricuspid Valve Regurgitation: Annulus, Commissure, or Leaflet Procedure? *Journal of Thoracic and Cardiovascular Surgery*. 2010; 1-10.
3. 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)
4. 2017 AHA/ACC Focused update of the 2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease

Figures

Figure 1

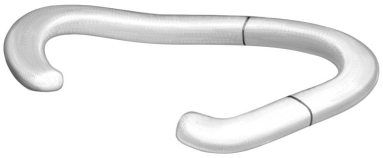


Figure 2

Figure 3

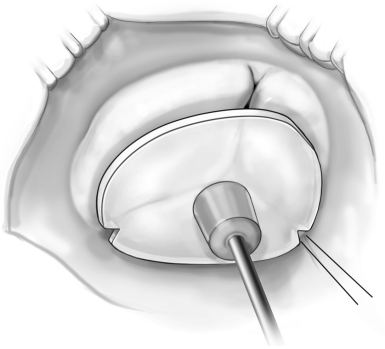


Figure 4

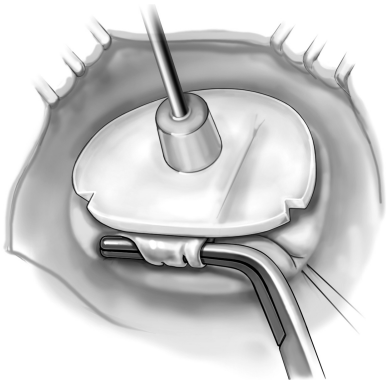


Figure 5

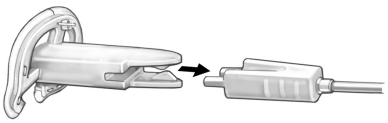
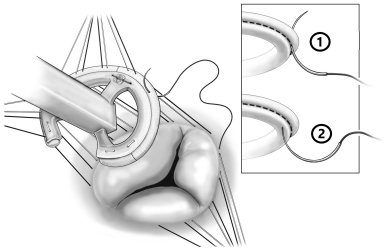


Figure 6



1. Correct
2. Incorrect

Figure 7

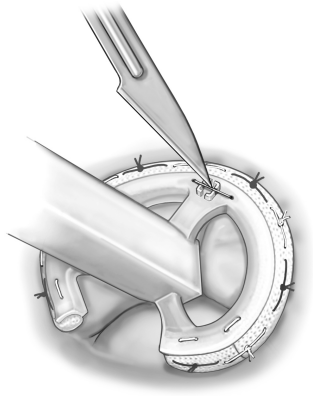


Figure 8

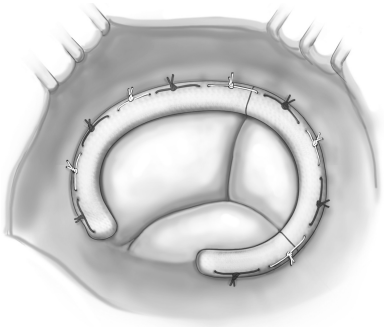


Figure 9

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

Edwards Lifesciences Services GmbH
Edisonstrasse 6
85716 Unterschleissheim
Germany

CE 0123

05/22
10052678001 A / DOC-0198263 A

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

Telephone 949.250.2500
800.424.3278
FAX 949.250.2525

Web IFU