Carpentier–Edwards Physio Tricuspid annuloplasty ring model 6200

For Single Use Only

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

1.0 Product Description

The Carpentier-Edwards Physio Tricuspid annuloplasty ring, model 6200, has a waveform contour core with selective flexibility that allows the ring to be compliant in the direction of flow while maintaining support of the tricuspid annulus to prevent further dilatation. The anteroseptal commissure is open to avoid the conduction system.

The ring is constructed of a titanium alloy core. The ring's sewing cuff consists of silicone rubber that is covered with a woven polyester cloth and polyethylene-tetrafluoroethylene 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 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 valvular insufficiency. It is intended to correct annular dilatation, increase leaflet coaptation, reinforce annular suture lines, and prevent further dilatation of the annulus.

3.0 Tricuspid Valve Reconstruction Techniques

The goal of tricuspid valve reconstruction is to preserve or restore normal leaflet motion, ensure a large surface of leaflet coaptation, and remodel the dilated and deformed annulus (Ref. 1). For specific techniques on tricuspid valve reconstruction, see the clinical literature in the References section (Refs. 1 & 2).

4.0 Contraindications

Use of the Carpentier-Edwards Physio Tricuspid annuloplasty ring is contraindicated in patients with the following conditions:

1. Severe organic lesions with retracted chordae.
2. Congenital malformation with lack of valvular tissue.
3. Large valvular calcifications.
4. Evolving bacterial endocarditis.

5.0 Warnings

5.1 For Single Patient Use Only

This device is designed, intended, and distributed for single use only. Do not reuse this device. There are no data to support the sterility, nonpyrogenicity and functionality of the device after reuse and reprocessing.

Physicians must ultimately make the decision whether to use an annuloplasty ring on a patient-by-patient basis after carefully evaluating the risks and benefits as compared to alternative methods for treatment. Each prospective patient must receive a full explanation of the benefits and risks before surgery.

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

Anticoagulation is recommended for the first three months after valvular repair surgery with an annuloplasty ring, unless contraindicated.

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

6.0 Precautions

Surgeons should have adequate training in valve repair, including ring implant and sizing techniques, before using this device. Training should include determining whether incompetent or diseased heart valves are capable of being repaired or if replacement is indicated. Surgeons should be current on all anticoagulation regimens. Additionally, it is important that the references herein be reviewed.

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.

7.0 Complications

Serious complications, sometimes leading to death, have been associated with the use of prosthetic 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 of the prosthetic device, sometimes within weeks or months.

Following is a list of complications associated with prosthetic ring annuloplasty compiled from the literature and from reports received through the complaint handling system in accordance with the U.S. (Federal) regulations establishing Good Manufacturing Practices, 21 CFR section 820.198:

- Failure or degeneration of the patient's natural valvular apparatus due to progression of the disease, endocarditis, or inadequate/incomplete repair of the valvular and subvalvular structures
- Malfunction of the ring due to distortion at implant or physical or chemical deterioration or fracture of ring components
- Bleeding diatheses related to the use of anticoagulation therapy
- Prolonged bypass, aortic cross clamping, and inadequate myocardial protection
- Residual or recurrent valvular insufficiency
- Tearing of the cloth covering with the use of cutting needles
- Thromboembolism
- Thrombosis
- Stenosis
- Damage to coronary arteries
- Right heart failure
- A-V block
- Hemolysis
- Low cardiac output
- Ring dehiscence
- Local and/or systemic infection

8.0 Instructions for Use

8.1 Physician Training

Surgeons should have adequate training in valve repair, including ring implant and sizing techniques, before using this device. Training should include determining whether incompetent or diseased heart valves are capable of being repaired or if replacement is indicated. Surgeons should be current on all anticoagulation regimens.

CAUTION: In addition to the information provided here, it is important that the references herein be reviewed.

8.2 Measurement and Selection of the Appropriate Ring

Step	Procedure
1	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). **CAUTION: Sizing the annulus is essential. Use only the appropriate tricuspid sizer provided by Edwards Lifesciences LLC to size the annulus.**
2	**WARNING: Fragments of the sizers cannot be located by means of an external imaging device.** **CAUTION: Examine sizers for signs of wear, such as dullness, cracking or crazing. If you observe any deterioration, replace the sizers immediately.** **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.** **CAUTION: Do not use the ring holder as a sizer.**

8.3 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).

Step	Procedure
1	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).
2	To bend the handle, grip the ends and gently apply force to bend the stainless steel shaft (Figure 3).
3	**WARNING: Fragments of the handle cannot be located by means of an external imaging device.** **CAUTION: Examine handle for signs of wear, such as dullness, cracking or crazing. If you observe any deterioration, replace the handles immediately.**

8.4 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.

Step	Procedure
1	Once you have selected the ring, place a series of horizontal mattress sutures at equidistant points around the tricuspid annulus. **WARNING: Avoid placing sutures in the atrial tissue or through the area of the Bundle of His, as this may impair cardiac conduction. Avoid placing sutures through the right coronary artery.** **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: To avoid damaging the fabric covering the ring, do not use metal forceps or suture needles with cutting edges during insertion.**
2	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.
3	Remove the serial number tag and parachute the ring.

8.5 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.

Step	Procedure
1	Cut the retaining suture thread in the raised area with a scalpel (Figure 8). This facilitates rapid removal of the ring from the holder. **WARNING: Do not cut any threads along the anterior portion of the ring. Cutting these threads can create loose threads with the potential for thromboembolism or hemolysis.**
2	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 annuloplasty ring from the holder after the ring is implanted. Implantation of the holder can cause patient injury or death. If a holder is lost within the surgical site, a radiopaque pin within the holder can be detected under x-ray.**
3	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 11.0 for cleaning and sterilization instructions.
4	Figure 9 illustrates a properly implanted annuloplasty ring.

8.6 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 remove the ring and replace the diseased valve with a prosthetic valve during the same procedure.

CAUTION: Careful and continuous medical follow-up is required so that prosthesis-related complications can be diagnosed and properly managed to minimize risk to the patient.

9.0 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 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.

10.0 Annuloplasty Ring

10.1 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.

10.2 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.

10.3 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 annuloplasty device after the expiration date on the label.

CAUTION: Gentle handling is required for all implantable devices.

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.

11.0 Accessories

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

Sizer/Handle Tray: Tricuspid model TRAY1262

Optional Holder Handles: model 1150 and model 1151

11.1 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.

11.2 Cleaning Instructions

All sizers, handles, trays and lids must be cleaned separately and sterilized prior to each use. Accessories should be replaced on a routine basis.

Contact your Edwards Lifesciences sales representative to obtain appropriate replacements.

CAUTION: Examine accessories for signs of wear, such as dullness, cracking or crazing. Replace sizer if any deterioration is observed.

WARNING: Fragments of the sizers and handles cannot be located by means of an external imaging device.

Instructions for Automated Cleaning:

Pre-rinse (as needed): Klenzyme enzymatic anionic detergent or equivalent.

Cleaning: Clean sizers and handles within tray and with lid detached prior to initial use and after each use with a nonionic detergent cleaning solution (example Instru-Klenz) in a mechanical washer (example STERIS AMSCO Reliance 444), minimum 2 minute wash phase.

Instructions for Manual Cleaning:

Pre-rinse (as needed): Per Hospital procedure.

Cleaning: Place the sizer, handle, tray base, and tray lid in a cleaning solution bath, such as Cidezyme, an enzymatic detergent, for the time and temperature specified by its manufacturer. Ensure that the instruments are covered and do not touch each other. Clean the accessories thoroughly with a soft plastic brush for 5 minutes; remove any superficial impurities with the soft brush. Never use metal brushes or steel wool on the instruments. Always use fresh cleaning solution between cleanings. Afterwards, rinse each accessory thoroughly 5 times for 1 minute with sterile, deionized water.

Disinfection: Place the cleaned and inspected instruments in disinfection solution (example Cidex OPA) for the time and temperature specified by the manufacturer. Ensure that the instruments are covered and do not touch each other. Afterwards, rinse each instrument thoroughly 5 times for 1 minute with sterile, deionized water.

11.3 Sterilization Instructions

Sizers must be disassembled from any threaded handles before resterilization.

CAUTION: Do not sterilize any of the accessories in their shipping containers. Accessories must be removed from their plastic pouches prior to sterilization. Each institution should use procedures that include biological indicators to determine the effectiveness of the sterilization procedure.

CAUTION: Do not stack trays during sterilization.

All accessory models can be sterilized using the following recommended autoclave sterilization methods:

Gravity Displacement:
Wrapped:

Temperature: 270 - 279 °F
(132 - 137 °C)

Exposure Time: 10-18 minutes

Unwrapped ("flash"):

Temperature: 270 - 279 °F
(132 - 137 °C)

Exposure Time: 3-18 minutes

Prevacuum:
Wrapped:

Temperature: 270 - 279 °F
(132 - 137 °C)

Exposure Time: 3-18 minutes

Unwrapped ("flash"):

Temperature: 270 - 279 °F
(132 - 137 °C)

Exposure Time: 3-18 minutes

The user is responsible for the qualification of any deviations from the recommended method of cleaning or sterilization.

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, 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.

12.2 Recovered Clinical Implants

Edwards Lifesciences LLC, is extremely interested in obtaining recovered clinical specimens of Carpentier-Edwards Physio Tricuspid rings for analysis. We will provide a written report summarizing our findings at the completion of our evaluation upon request. 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.

Prices and model availability are subject to change without notice.

13.0 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.

Figures

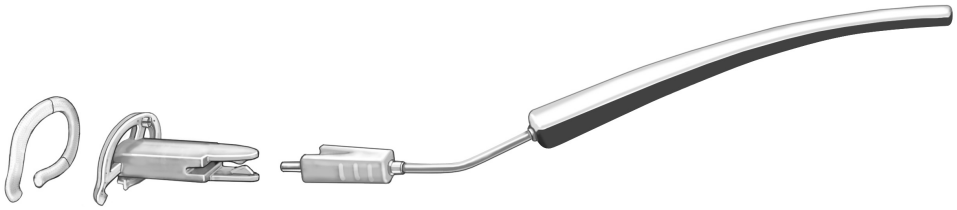


Figure 1

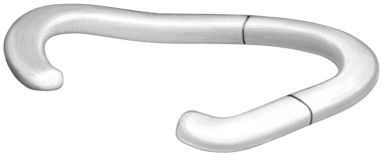
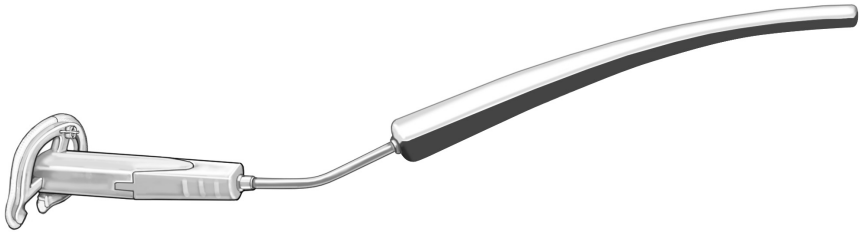


Figure 2



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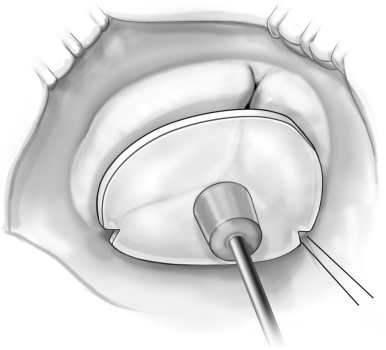
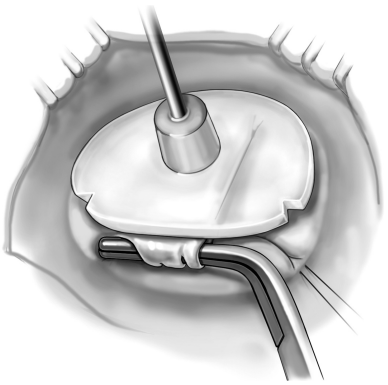


Figure 4



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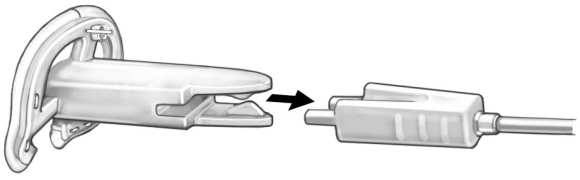
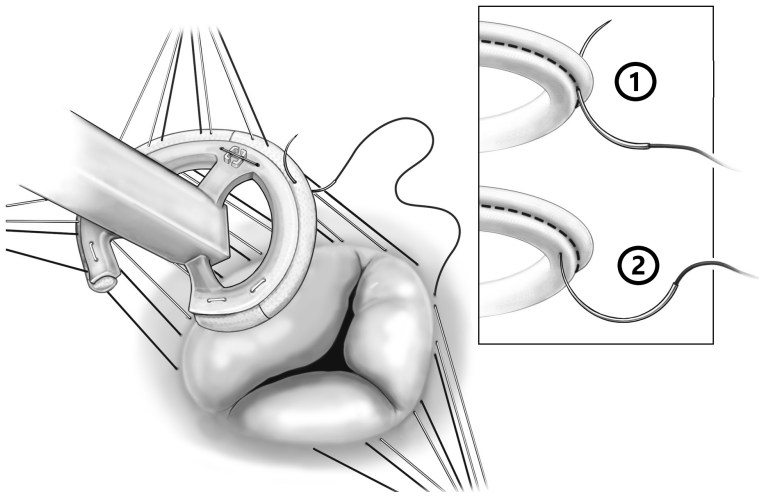


Figure 6



1. Correct
2. Incorrect

Figure 7

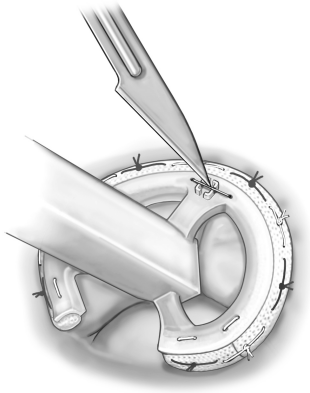


Figure 8

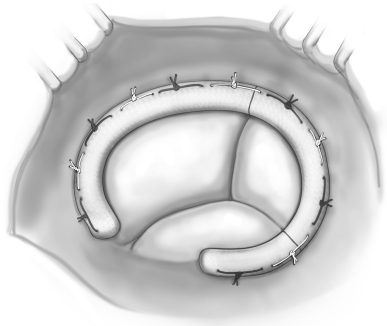


Figure 9

Symbol Legend

	ISO Reg. No.[1]	English
	2493	Catalogue Number
	0434A	Caution
	1641	Consult instructions for use
	1641	Consult instructions for use on the website
	1051	Do not re-use
	2608	Do not resterilize
	N/A	Quantity
	2607	Use-by date
	2498	Serial Number

	ISO Reg. No.[1]	English
	3082	Manufacturer
	2497	Date of manufacture
	N/A	MR Conditional
	2724	Non-pyrogenic
	2606	Do not use if package is damaged
	2503	Sterilized using steam or dry heat
	N/A	Store in a cool, dry place
Rx only	N/A	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Note: The labeling of this product may not contain every symbol depicted in the legend.

[1] ISO 7000 *Graphical symbols for use on medical equipment - Registered symbols*

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