Carpentier-Edwards Physio Annuloplasty Ring Mitral Model 4450 with Holder

For single use only

1.0 Concept/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.

The design 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 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.

1.1 Ring Valvuloplasty Techniques

Techniques, described in detail in the literature as referenced, are applicable to the correction of mitral insufficiency; the techniques allow remodeling of the valvular apparatus with a tailored prosthetic ring of appropriate size and shape. The ring is placed in the atrium and sutured to the natural annulus.

The technique repositions displaced and incompetent valvular cusps, remodels the distended cusps and commissures, and reduces annular dilatation by staged plication at several points.

Clinical results with use of prosthetic rings indicate a reduction in thromboembolic risk, as compared to valvular replacement, and elimination of the need for long-term postoperative anticoagulation therapy in most patients (see **References**).

When compared with other techniques, prosthetic ring annuloplasty offers the following advantages:

1. Correction of dilatation as well as deformation of the valvular annulus, conserving optimal orifice area.
2. Selective reduction of dilated and deformed zones preserving normal leaflet function.
3. Correction based on precise measurement of the valvular apparatus providing a predictable result.
4. Prevention of recurrent dilatation or deformation.

Additional features of annuloplasty rings include:

1. Transverse colored thread facilitates location of the commissures and proper positioning of the ring.
2. Small size and profile of the rings minimize the exposure of foreign material in the atrium and may account for the reduced thromboembolic incidence as compared with prosthetic valves.

2.0 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.

The Carpentier-Edwards Physio annuloplasty ring is intended to meet the challenges of modern valvuloplasty by maintaining the physiologic annular shape and motion. The annuloplasty ring is designed to follow the functional changes which occur during the cardiac cycle, thereby maintaining coaptation and valve integrity in systole while permitting good hemodynamics in diastole.

The decision to undertake annuloplasty can be made only after visual analysis of the lesion present. The most favorable conditions for annuloplasty using a prosthetic ring are a combination of the distended natural valve ring associated with supple valve cusps and normal chordae tendineae.

The remodeling annuloplasty technique with a Carpentier-Edwards Physio annuloplasty ring, Model 4450, may be used in all acquired or congenital mitral insufficiencies with dilatation and deformation of the fibrous mitral

annulus, with the exception of severe congenital malformations (e.g., AV canal or hypoplastic commissures) or severe degenerative valvular diseases where there is considerable excess tissue.

For Type I mitral insufficiencies with no subvalvular lesions and normal valvular movements, this ring technique used alone is sufficient. However, the ring technique must be associated with mitral valvuloplasty repair in Type II insufficiencies with a prolapsed valve due to elongation or rupture of the chordae tendineae or papillary muscle and in Type III insufficiencies with limitation of valvular movements due to fusion of the commissures or chordae, or chordal hypertrophy.

3.0 Contraindications

- Severe organic lesions with retracted chordae.
- Congenital malformations with lack of valvular tissue.
- Large valvular calcifications.
- Evolving bacterial endocarditis.

4.0 Warnings

4.1 For Single Patient Use Only

The decision to use an annuloplasty ring must ultimately be made by the physician on an individual basis after carefully evaluating the short- and long-term risks and benefits to the patient as compared to alternative methods of treatment.

It is recommended that anticoagulants be used for the first two months postoperatively, except where contraindicated, to promote a gradual healing of the exposed cloth and sutures.

Recipients of annuloplasty rings who are undergoing dental or other surgical procedures should receive prophylactic antibiotic therapy to minimize the possibility of systemic infection.

Do not attempt to deform or otherwise alter the configuration of the annuloplasty ring to conform to a specific annular anatomy, as this could damage the ring. If the ring is not suitably sized for the annulus, a larger or smaller ring should be chosen.

5.0 Precautions

Before clinical application, surgeons should become familiar, by appropriate training, with the surgical technique and its variations. In addition to the information provided here, it is important that the references listed herein be reviewed.

A serial number tag is attached to the annuloplasty ring by a suture. This tag should not be detached from the annuloplasty ring until implant is imminent. Care should be exercised to avoid cutting or tearing of the cloth during removal of the tag.

To avoid damage to the fabric covering the ring, suture needles with cutting edges and metal forceps must not be used during insertion.

Sutures should be placed no more than 1.5 mm away from the external diameter of the sewing ring. (See Suture Placement in Instructions for Use.)

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.**

To ensure the sterility and integrity of the annuloplasty ring, the ring should be stored in the outer cardboard box until use is imminent. Gentle handling is required for all implantable devices. Rings that have been removed from the double trays and dropped, soiled, or are suspected of being damaged should not be used.

Sizing the annulus properly is essential. Use only the appropriate sizers provided by Edwards to size the annulus. Do not attempt to use ring holder as a sizer.

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.

6.0 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 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 (sometimes within weeks or months) of the prosthetic device.

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

Complications associated with prosthetic ring valvuloplasty compiled from the literature and from reports received through the complaint handling system in accordance with the United States (Federal) regulations establishing Good Manufacturing Practices, 21 CFR section 820.198, include: residual or recurrent valvular insufficiency; stenosis; thromboembolism; hemolysis; A-V block; low cardiac output; right heart failure; 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; suture obliteration of the circumflex coronary artery; complications related to prolonged bypass, aortic cross clamping and inadequate myocardial protection; partial dislodgement of the ring from its site of attachment (ring dehiscence); malfunction of the ring due to distortion at implant or physical or chemical deterioration of ring components; fracture of the ring components; tearing of the cloth covering with the use of cutting needles; fraying of the suture material and eventual suture breakage upon incorrect placement of sutures into the ring; bleeding diatheses related to the use of anticoagulation therapy; systolic anterior motion (S.A.M.) and left ventricular outflow tract obstruction (L.V.O.T.O.) whenever a large posterior leaflet is present; and local and/or systemic infection.

7.0 Instructions for Use

7.1 Measurement and Selection of the Appropriate Ring

Because the technique of valvular remodeling 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 (less than 5%), 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.

The most commonly used sizes are 30 mm and 32 mm in women, and 32 mm and 34 mm in men.

7.2 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 quick 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.

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.

7.3 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.

7.4 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 external diameter 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 external diameter 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.**

7.5 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.

7.6 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 must be prepared to remove the ring and replace the diseased valve with a prosthetic valve during the same procedure.

8.0 Annuloplasty Ring

8.1 Specifications

Carpentier-Edwards Physio annuloplasty ring with holder Model 4450

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

8.2 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.

8.3 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.

9.0 Accessories

9.1 Specifications

Optional Handle Model 1150

9.2 Sizers/Handles (Push Fit Connection)

Push Fit Mitral Sizers Model 1164
Sizes: M24 - M40

Push Fit Sizer Handle Model 1146

9.3 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.

9.4 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.

9.5 Cleaning Instructions

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

Cleaning: Clean tray and lid separately prior to initial use and after each use with a nonionic detergent cleaning solution (example Instruklenz) in a mechanical washer (example STERIS AMSCO Reliance 444).

Ultrasonic cleaning should not be used to clean the Model 1150 handle. This process can cause crazing and cracking of the plastic material.

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

9.6 Sterilization Instructions

Sizers and sizer handles must be disassembled before sterilization. The accessories should be examined for signs of wear, such as dullness, cracking, or crazing, and should be replaced if deterioration is observed.

The following conditions are recommended for the sterilization of the accessories.

9.6.1 Autoclave Sterilization

Gravity Displacement:
Wrapped:
Temperature: 270 °F-275 °F (132 °C-135 °C)
Exposure Time: 10-15 minutes

Unwrapped ("flash"):
Temperature: 270 °F (132 °C)
Exposure Time: 3 minutes

Prevacuum:
Wrapped:
Temperature: 270 °F-275 °F (132 °C-135 °C)
Exposure Time: 3-4 minutes

Unwrapped ("flash"):
Temperature: 270 °F (132 °C)
Exposure Time: 3 minutes

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

Do not stack trays during sterilization.

10.0 Case History

10.1 Implant Patient Registry

When a 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.

10.2 Recovered Clinical Implants

Edwards Lifesciences LLC, is extremely interested in obtaining recovered clinical specimens of Carpentier-Edwards Physio annuloplasty rings for analysis. A written report summarizing our findings will be provided upon completion of our evaluation. 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.

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

Prices and model availability are subject to change without notice.

11.0 References

1. Carpentier, A. "Cardiac Valve Surgery - The French Correction". *J. Thorac. Cardiovasc. Surg*., 86:323-337, 1983.
2. Carpentier, A.F. The "Physio-Ring": An Advanced Concept in Mitral Valve Annuloplasty. *Ann. Thorac. Surg*., 60:1177-1186, 1995.
3. Chauvaud, S., et al. "Long-Term Results of Valve Repair in Children with Acquired Mitral Valve Incompetence". *Circulation*, 74 (suppl I):104-109, 1986.
4. Deloche, A., et al. "Valve Repair with Carpentier Techniques - The Second Decade". *J. Thorac. Cardiovasc. Surg*., 99:990-1002, 1990.
5. Galloway, A.C., et al. "A Comparison of Mitral Valve Reconstruction with Mitral Valve Replacement: Intermediate-Term Results". *Ann. Thorac. Surg*., 47:655-662, 1989.

Figures

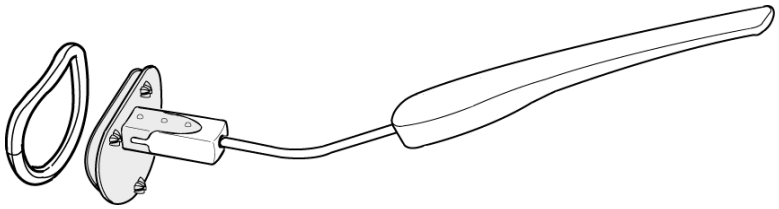


Figure 1: Use of holder and ring handle is optional

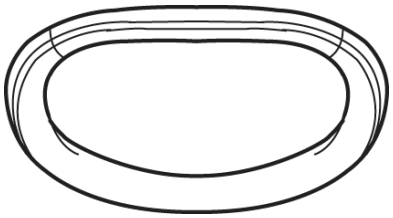


Figure 2

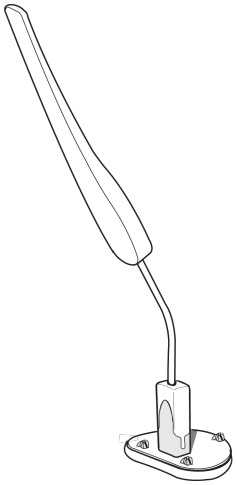


Figure 3

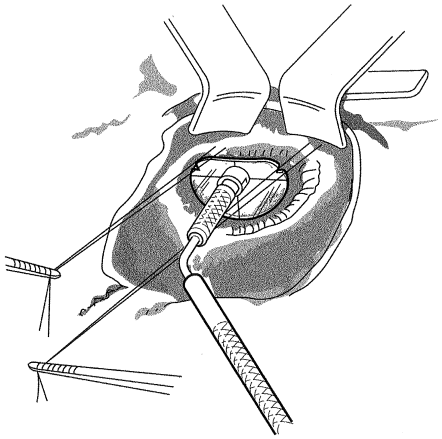


Figure 4

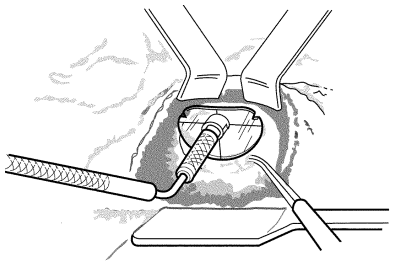


Figure 5

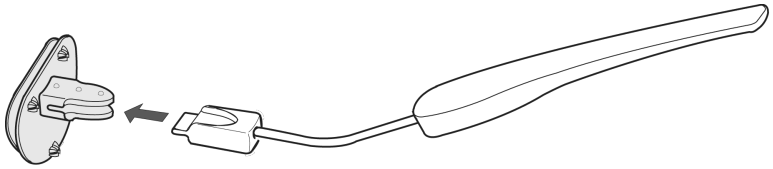


Figure 6

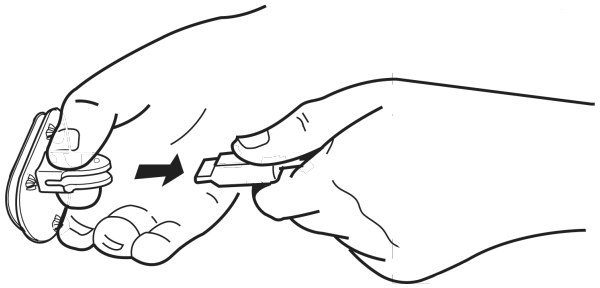


Figure 7

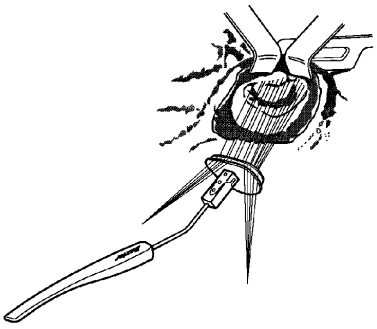
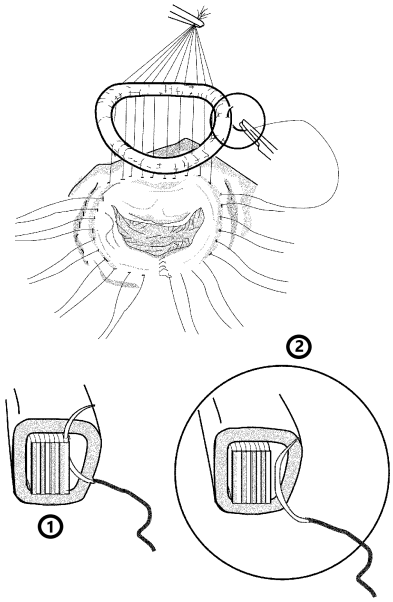


Figure 8



1. INCORRECT
2. CORRECT

Figure 9

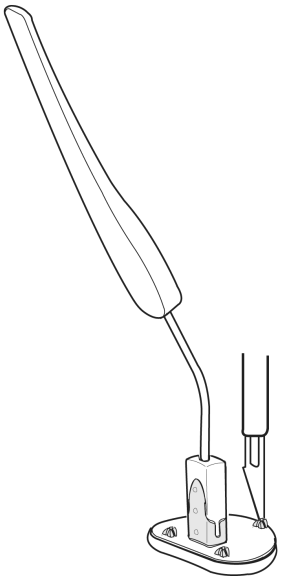


Figure 10

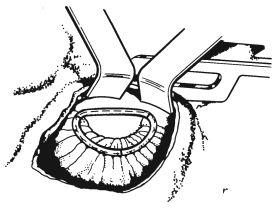


Figure 11

Symbol Legend

	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*

04/22
10051789001 A

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

Telephone 949.250.2500
800.424.3278
FAX 949.250.2525

Web IFU