Carpentier-McCarthy-Adams IMR ETlogix Annuloplasty Ring Mitral Model 4100 with Holder

For Single Use Only

1.0 Concept/Description

The IMR ETlogix annuloplasty ring, mitral Model 4100 is constructed of titanium alloy and has a sewing ring margin that consists of a layer of silicone rubber covered with a woven polyester cloth. Design objectives include: retention of the natural valve apparatus, remodeling of the annulus, retention of a normal valve orifice during systole, and prevention of secondary distension of the annulus (frequently the cause of recurrent incompetence after conventional valvuloplasties). The small size and profile of the ring minimize the exposure of foreign material in the atrium and may account for the reduced thromboembolic incidence as compared with prosthetic valves.

Transverse colored threads indicate the anterior and posterior commissures to facilitate proper positioning of the ring (Figure 2).

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 MRI (Magnetic Resonance Imaging) Compatibility

The device has been shown not to have magnetic interactions at up to 8 tesla. It is also safe with respect to RF heating at 1.2 W/kg for up to 15 minutes. Artifacts have been determined at 1.5 tesla.

1.2 Ring Valvuloplasty Techniques

Established surgical techniques can be used in correction of mitral valvular insufficiencies. The ring is placed in the atrial position and sutured to the natural annulus.

The techniques reposition displaced and incompetent valvular cusps, remodel the distended cusps and commissures, and reduce annular dilatation by staged plication at several points.

When compared with other techniques, prosthetic ring valvuloplasty 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.

Clinical results 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.

2.0 Indications

The IMR ETlogix annuloplasty ring is indicated for the correction of mitral valvular insufficiency where the lesions are not so severe as to require total valve replacement.

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

The remodeling valvuloplasty technique with a prosthetic ring may be used in all acquired or congenital mitral insufficiencies with dilatation and deformation of the fibrous mitral annulus.

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 and in Type III insufficiencies with limitation of valvular movements due to fusion of the commissures or chordae tendineae, or chordal hypertrophy.

3.0 Contraindications

1. Severe organic lesions with retracted chordae
2. Congenital malformations with lack of valvular tissue
3. Large valvular calcifications
4. 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 procedures 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 guidelines provided here, it is important that the references listed herein be reviewed.

A serial number tag is attached to the prosthesis by a suture. This tag should not be detached from the prosthesis 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.

For ease of orientation, the sewing ring is marked with a colored thread (Figure 2). **This side of the ring must lie 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 Edwards 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 should be given to each prospective patient before surgery.

Serious complications, sometimes leading to death, have been associated with the use of annuloplasty 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 advised so that prosthesis-related complications can be diagnosed and properly managed to minimize danger to the patient.

Complications associated with annuloplasty 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, 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 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 dislodgment of the ring from its site of attachment; malfunction of the ring due to distortion at implant or physical or chemical deterioration of ring components; tearing of the cloth covering with the use of cutting needles; bleeding diatheses related to the use of anticoagulant therapy; and systolic anterior motion (S.A.M.) and left ventricular outflow tract obstruction (L.V.O.T.O.) whenever a large posterior leaflet is present.

7.0 Instructions for Use

7.1 Measurement and Selection of the Appropriate Ring

This annuloplasty ring incorporates an asymmetrical design for optimal restoration of mitral competency in valves with functional mitral insufficiency. It is recommended that the following technique be used to measure and select the appropriate sized IMR ETlogix annuloplasty ring.

Because the intention of the technique of valvular remodeling is to restore a mitral competency, measurement and ring selection is based on the measurement of the anterior leaflet attachment by using sizers with two notches on their linear segments (Figure 4). Since the delineation of the anterior leaflet may be difficult, 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.

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 (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 (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 Prosthesis

Insertion of the mitral prosthesis can be done by interrupted horizontal sutures in the fibrous mitral annulus 2 mm from the leaflet hinge.

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 prosthetic ring should be maintained (Figure 8).

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

For patients with asymmetric annular dilatation concentrated in the P2-P3 (posterior) region of the mitral annulus, application of an additional row of horizontal interrupted sutures is recommended to secure the ring to the fibrous mitral annulus. The IMR ETlogix annuloplasty ring has an increased sewing margin in the P2-P3 (posterior) region, marked with a suture, designed to accommodate a double-suture-row (Figure 9).

7.4 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.

7.5 Testing

Valvular competency is tested by injecting saline into the left ventricle through the mitral orifice. Intraoperative echo has been instrumental in assessing valvular competency and the quality of repair.

If use of established surgical techniques in conjunction with ring annuloplasty 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

IMR ETlogix annuloplasty ring with holder, Model 4100

Sizes: 24 mm, 26 mm, 28 mm, 30 mm, 32 mm, 34 mm.

8.2 How Supplied

IMR ETlogix annuloplasty ring with attached holder is provided sterile and nonpyrogenic in 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 prosthesis should be stored in the outer cardboard box in a dry, contamination free area until needed. Stock rotation at regular intervals is recommended to ensure usage of the ring before the expiration date stamped on the label. The annuloplasty ring cannot be used after the date stamped on the package.

9.0 Accessories

9.1 Specifications

Optional Handle Model 1150

9.2 Sizers/Handles (Threaded Connection)

Mitral Sizers
Model 1174
Sizes Available: M24 through M34

Handle for use with Sizers
Model 1111 and Model 1126

9.3 Trays

Mitral Sizer/Handle Tray
Model TRAY1174

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

9.4 How Supplied

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

Sizers corresponding to the various sizes of mitral rings are available (See Specifications). These sizers should be used

at the time of operation for accurate selection of the appropriate size ring for each 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.

9.6 Sterilization Instructions

The sizers and sizer handles are intended for multiple use as long as they are properly handled and inspected before using. 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.

Autoclave Sterilization:

Gravity Displacement:
Wrapped:
Temperature: 270 °F-279 °F (132 °C-137 °C)
Exposure Time: 10-15 minutes

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

Prevacuum:
Wrapped:
Temperature: 270 °F-279 °F (132 °C-137 °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 sterilization.

Do not stack trays during sterilization.

10.0 Case History

10.1 Implant Patient Registry

When each Edwards annuloplasty ring is used, carefully complete the Implantation Data Card that is packaged with each device. Return the pre-addressed 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 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 the IMR ETlogix 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 under these circumstances.

Kits to return the explanted rings are available upon request.

CAUTION: Federal law (USA) 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. Chauvaud, S., et al. Long-Term Results of Valve Repair in Children with Acquired Mitral Valve Incompetence. *Circulation*, 74 (suppl I):104-109, 1986.
3. Deloche, A., et al. Valve Repair with Carpentier Techniques: The Second Decade. *J. Thorac. Cardiovasc. Surg*., 99:990-1002, 1990.
4. Galloway, A.C., et al. A Comparison of Mitral Valve Reconstruction with Mitral Valve Replacement: Intermediate-Term Results. *Ann. Thorac. Surg*., 47:655-62, 1989.
5. Perier, P., et al. Comparative Evaluation of Mitral Valve Repair and Replacement with Starr, Bjork, and Porcine Valve Prostheses. *Circulation*, 70 (suppl I): 187-192, 1984.

Figures

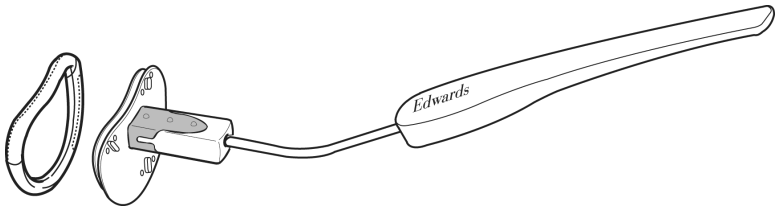


Figure 1: Use of holder and ring handle is optional

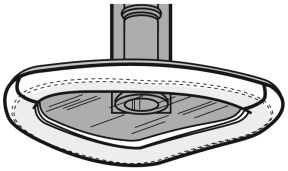


Figure 2

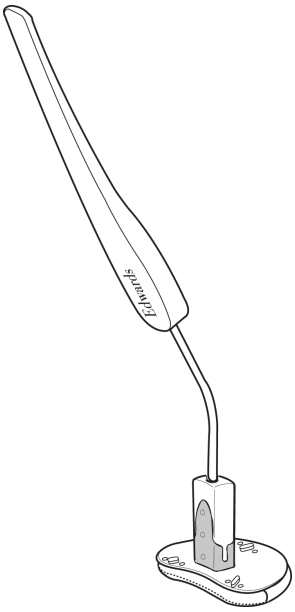


Figure 3

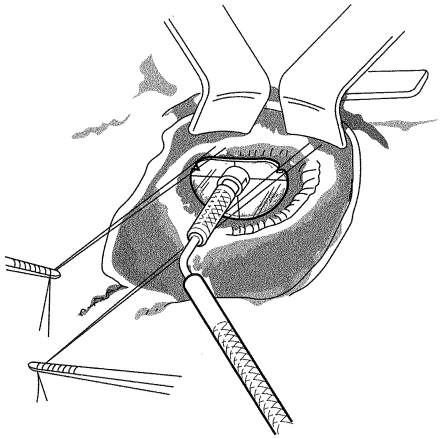


Figure 4

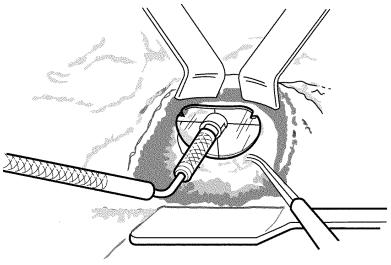


Figure 5

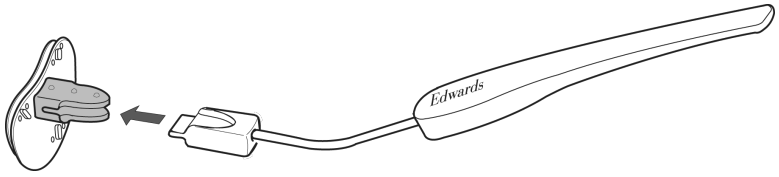
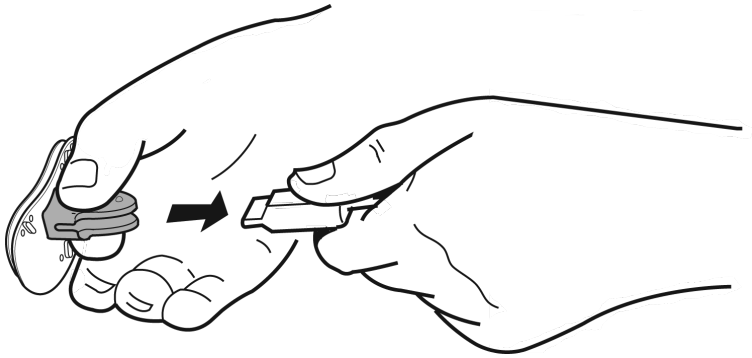


Figure 6



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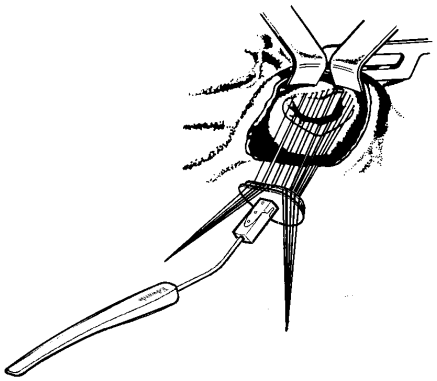

Figure 8

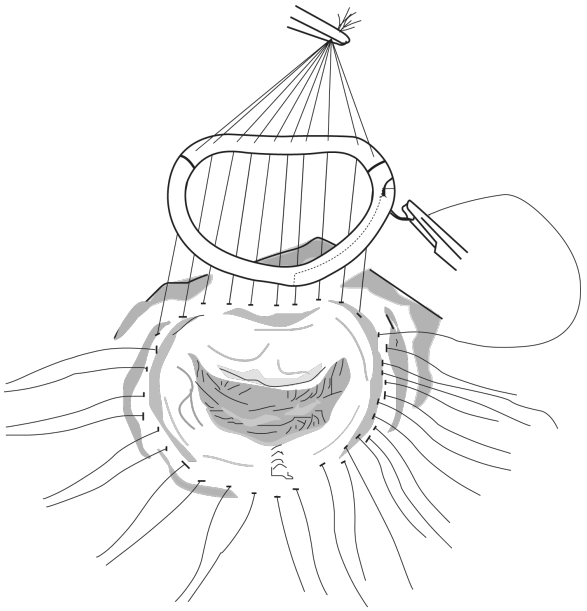

Figure 9

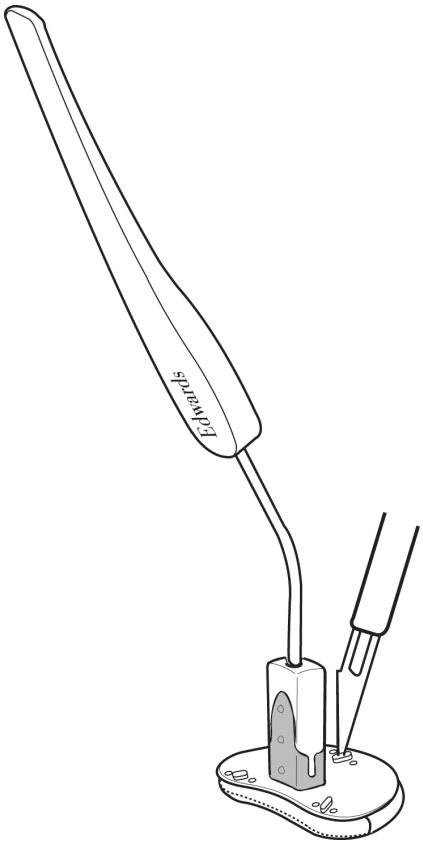

Figure 10

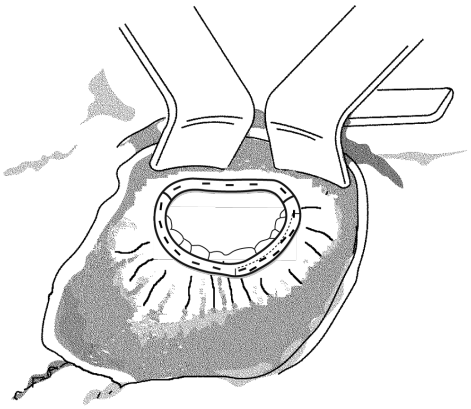

Figure 11

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*

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