Edwards

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

For Single Use Only

1.0 Product 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.

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.

2.0 Safety in the Magnetic Resonance (MR) Environment

MR Conditional

Non-clinical testing has demonstrated that the IMR ETlogix annuloplasty ring, model 4100, is MR Conditional. A patient with the IMR ETlogix annuloplasty ring, model 4100, 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, the IMR ETlogix annuloplasty ring, model 4100, produced a temperature rise of less than or equal to 1.6 °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 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.

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.

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.

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 4100 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.

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). **This side of the ring must lie 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.

8.0 Instructions for Use

Measurement and Selection of the Appropriate Ring

This annuloplasty ring incorporates an asymmetrical design. It is recommended that the following technique be used to measure and select the appropriate sized IMR ETlogix annuloplasty ring.

Because the intention 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.

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.

8.1 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. 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.

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).

8.2 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 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.

8.3 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 should consider alternative treatment options.

9.0 Annuloplasty Ring

9.1 Specifications

IMR ETlogix annuloplasty ring with holder, Model 4100

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

9.2 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.

9.3 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.

10.0 Accessories

Specifications

Optional Handle Model 1150

Sizers/Handles (Threaded Connection)

Mitral Sizers
Model 1174
Sizes Available: M24 through M34

Handle for use with Sizers
Model 1111 and Model 1126

Trays

Mitral Sizer/Handle Tray
Model Tray1174

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

10.1 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.

10.2 Cleaning and Sterilization Instructions

For the 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 each Edwards 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 the implantation data card should be used to report this information to our Registry.

11.2 Recovered Clinical Implants

Edwards Lifesciences LLC is extremely interested in obtaining recovered clinical specimens of the IMR ETlogix 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 under these circumstances.

Kits to return the explanted rings are available upon request.

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 IMR ETlogix annuloplasty ring, model 4100. 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 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

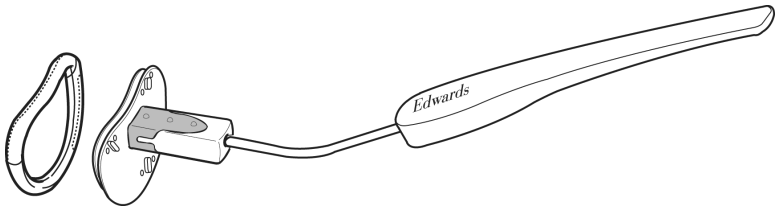


Figure 1: Use of holder and ring handle is optional

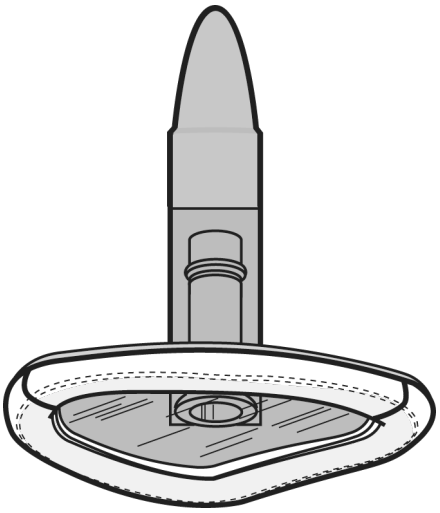


Figure 2

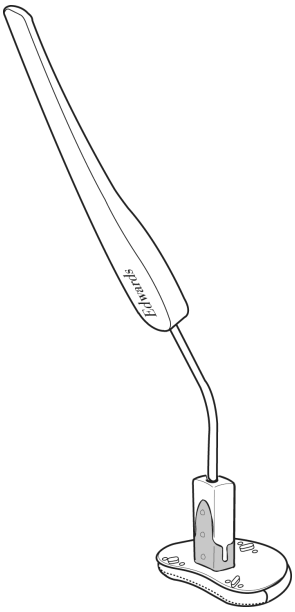


Figure 3

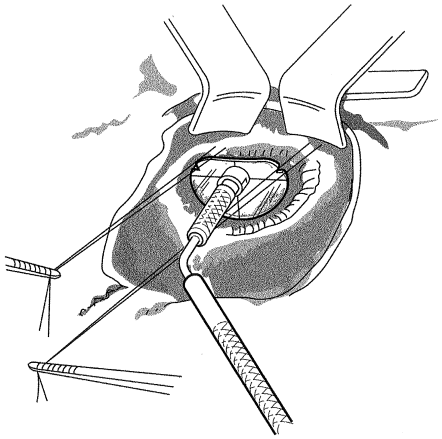
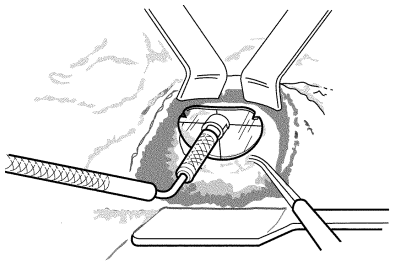


Figure 4



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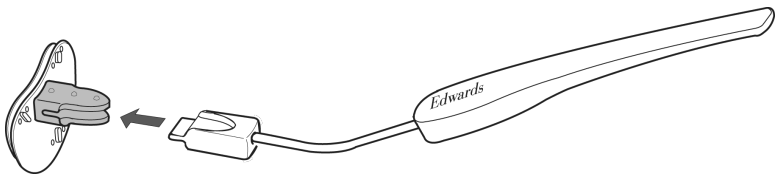
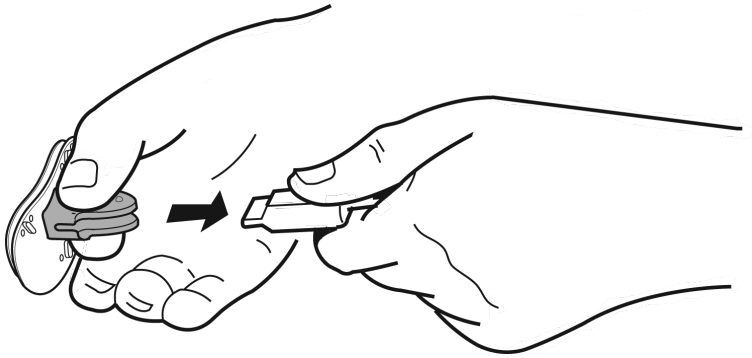


Figure 6



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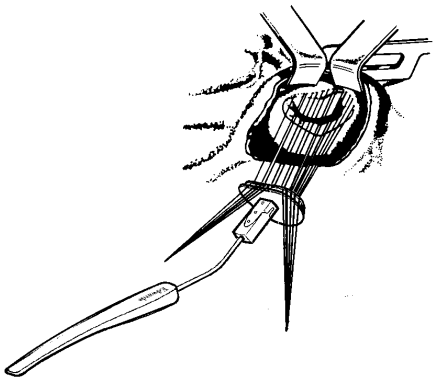

Figure 8

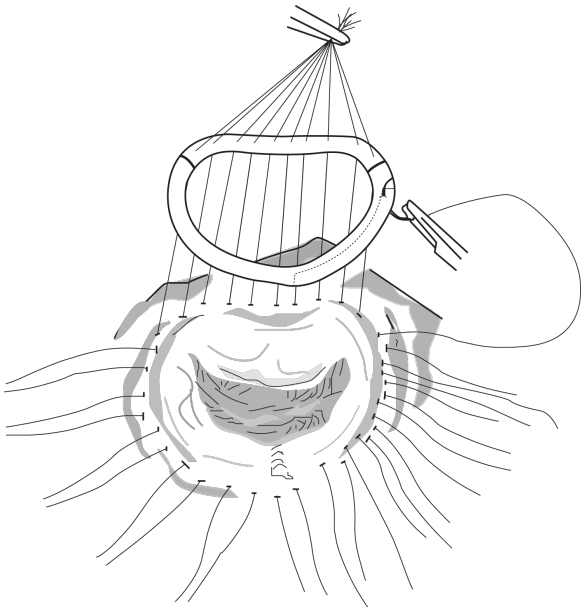

Figure 9

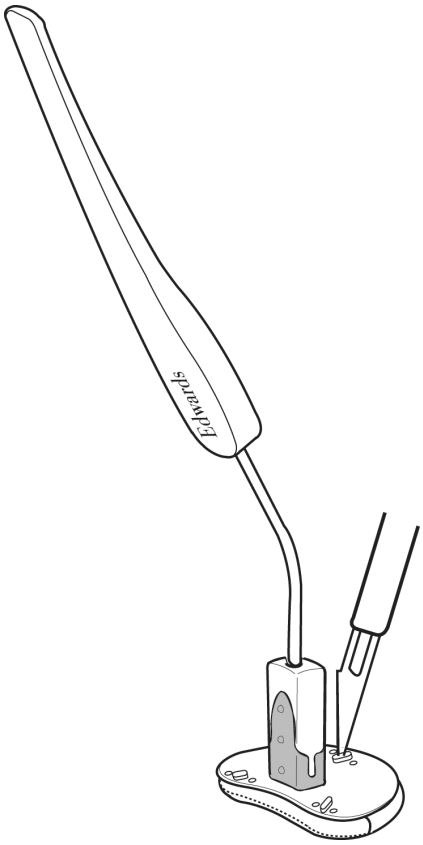

Figure 10

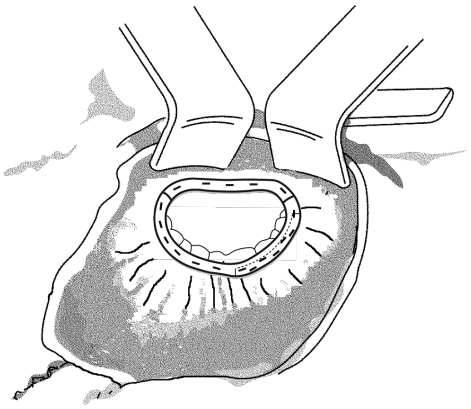

Figure 11

Symbol Legend

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

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