Edwards

Edwards MC3 Tricuspid Annuloplasty Ring with Template/Lanyard for Valvuloplasty

Model 4900

For Single Use Only

1.0 Product Description

The Edwards MC3 Tricuspid annuloplasty ring, Model 4900, consists of two primary components: the implantable annuloplasty ring and the template/ lanyard assembly (or holder). An optional handle, Model 1150, is available separately (Figure 1).

The implantable annuloplasty ring is constructed of titanium alloy and has a sewing ring margin that consists of a layer of silicone rubber, covered with polyester velour cloth sewn with a single seam.

The Edwards MC3 Tricuspid annuloplasty ring can be used in tricuspid valve repairs. The oval tricuspid ring conforms to the configuration of a normal tricuspid orifice. The ring has one rectilinear segment corresponding to the septal leaflet and one long curved segment corresponding to the anterior and posterior leaflets. The ring is open at the anteroseptal commissure (Figure 2).

The annuloplasty ring is provided on an integral template which holds the ring during the plication of the annulus.

A feature of the Edwards MC3 Tricuspid annuloplasty ring is that the rigid template is designed not to interfere with the tying of sutures and contains a retrieval system during the removal process (see **Annuloplasty Ring/Template-Lanyard Assembly**).

After implantation, this rigid template is removed.

The Model 1150 handle may be utilized to facilitate ease of suture placement and annuloplasty ring implantation. The snap-fit assembly of the handle and template/lanyard assembly allows for connecting and disconnecting of the two components.

2.0 Safety in the Magnetic Resonance (MR) Environment

MR Conditional

Non-clinical testing has demonstrated that the Edwards MC3 Tricuspid annuloplasty ring (model 4900), is MR Conditional. A patient with the Edwards MC3 Tricuspid annuloplasty ring (model 4900) can be scanned safely, immediately after placement of this implant under the following conditions:

- Static magnetic field of 3 tesla or less
- Maximum spatial magnetic gradient field of 720 gauss/cm
- 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, Edwards MC3 Tricuspid annuloplasty ring (model 4900), produced a temperature rise of less than or equal to 0.6 °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 Edwards MC3 Tricuspid annuloplasty ring, Model 4900, is intended for use in patients to correct annular dilatation, increase leaflet coaptation, reinforce annular suture lines, and prevent further dilatation of the annulus.

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 4900 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.

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.

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.

7.0 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 (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.

8.0 Instructions for Use

8.1 Annuloplasty Ring/Template-Lanyard Assembly

The annuloplasty ring is provided mounted to a disposable template. The annuloplasty ring is mounted on the template with three white retaining sutures in order to provide visualization against the template (Figure 5).

A unique template/lanyard assembly is provided to facilitate implantation of the annuloplasty ring. To avoid interference with suture tying by a holder or handle, a lanyard of monofilament thread connects the post to the template. At the appropriate time during surgery, the post

may be disconnected from the template by means of two simple suture cuts.

An internal spool of monofilament thread, located within the post of the template, will release a length of thread long enough to remove the post from the surgical field while still being connected to the template/ annuloplasty ring assembly. The internal spool of monofilament thread also presents a means of preventing the template from dropping into the right ventricle during the removal process (Figure 6).

8.2 Template-Lanyard Assembly and Handle Connection

To accommodate the handle, the template incorporates a post with a snap-fit connection point for the handle. The handle, available separately, may be connected to the template assembly by snapping the two components together (Figure 7). The middle section of the handle is malleable, allowing the handle to be adjusted (bent) in a configuration convenient for use (Figure 8). The template assembly and handle may remain attached until the annuloplasty ring is in place or, prior to lowering the annuloplasty ring into the heart, the handle may be disconnected from the post of the template by holding the post at the connection point while pulling the handle (Figure 7). The surgeon may then position the annuloplasty ring by holding the post at the connection point (Figure 9). The post section of the template/lanyard assembly and the handle (if used) may be removed from the surgical site by cutting the two retaining sutures on the template, as described above.

8.3 Tricuspid Position

Measurement and Selection of the Appropriate Annuloplasty Ring

Because the intention of the technique is to restore a physiological orifice, measurement and ring selection are important aspects of the operation.

Ring selection must be based on the measurement of the septal leaflet attachment by using sizers with two notches on their linear segment (Figure 10).

Since the delineation of the septal leaflet may be difficult, the ring can also be selected by measuring the surface of the anterior leaflet using the same sizers. To facilitate this measurement, the chordae tendineae rising from the anterior papillary muscle may be pulled out with a nerve hook, thus spreading the leaflet.

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

Insertion of the Prosthesis

The insertion of the prosthesis can be carried out by interrupted horizontal mattress sutures in the fibrous tricuspid annulus (Figures 10 through 12). Care should be taken to avoid placing a suture through the area of the Bundle of His.

To facilitate exposure of the tricuspid annulus and to avoid catching the chordae tendineae by a suture, the following procedure should be followed. The leaflet should be tensed perpendicular to the atrial wall when passing the needle through the annulus towards the ventricular cavity and then towards the atrium.

Whatever the technique used, the principles remain the same:

1. Precise relationship among leaflets and corresponding segments of the prosthetic ring should be maintained.
2. Sutures should be placed through the annulus 2 mm from the leaflet hinge to preserve leaflet function.
3. The first suture should be placed at the midpoint of the septal leaflet.

9.0 Annuloplasty Ring Template Removal

Three raised areas with slots are provided to permit the surgeon to cut the retaining sutures with a scalpel. This facilitates removal of the annuloplasty ring from the template (Figure 13). The retaining sutures are permanently connected to the template; upon withdrawal of the template, all retaining sutures are removed. After the template is detached from the annuloplasty ring, the template is to be discarded. The handle may be reused.

The template must be removed from the ring. Implantation of the template can cause patient injury or death. In the event that a template needs to be located within the surgical site, its presence can be detected under x-ray.

Testing

For tricuspid valve repairs, intraoperative echo has been instrumental in assessing valvular competency and the quality of repair.

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 sizing and insertion of the annuloplasty ring fails to produce adequate repair of valvular insufficiency as determined by visual inspection and/or intraoperative testing, the surgeon should consider alternative treatment options.

10.0 Annuloplasty Ring with Template/ Lanyard

10.1 Specifications

Edwards MC3 Tricuspid annuloplasty ring with Template/ Lanyard for tricuspid valve repairs, Model 4900

Sizes: 26 mm, 28 mm, 30 mm, 32 mm, 34 mm, 36 mm

10.2 How Supplied

The Edwards MC3 Tricuspid annuloplasty ring with Template/Lanyard 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, the annuloplasty ring/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.

11.0 Accessories

Specifications

Annuloplasty Ring Handle Model 1150

Sizers/Handles (Threaded Connection)

Threaded Tricuspid Sizers Model 1175 Sizes: T26–T36

Threaded Sizer Handle Model 1111

Sizer/Handle Tray – Tricuspid Model TRAY1175

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

11.1 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.

11.2 Cleaning and Sterilization Instructions

For cleaning and sterilization of listed accessory models refer to the Instructions for Use provided with the Accessories.

12.0 Case History

12.1 Implant Patient Registry

When an Edwards annuloplasty product 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 the hospital and surgeon records. Upon receipt by the Registry, a wallet-sized identification card will be produced for the patient. This card allows patients to inform health care providers what type of device they have when they seek care. When an Edwards device is discarded, the implantation data card should be used to report this information to our Registry.

12.2 Recovered Clinical Implants

Edwards is extremely interested in obtaining recovered clinical specimens of annuloplasty rings for analysis. Please contact your local company representative for return of recovered annuloplasty rings. The annuloplasty 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 explanted rings are available upon request.

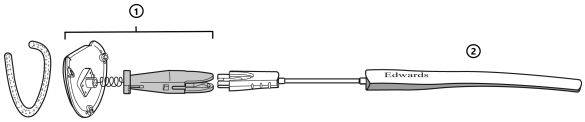
13.0 Physician Training

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 Edwards MC3 Tricuspid annuloplasy ring, model 4900. It is the surgeon's decision when and if to repair a tricuspid valve.

14.0 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 Disease of the European Society of Cardiology (ESC) and the European 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



1. Template/Lanyard Assembly
2. Handle

Figure 1

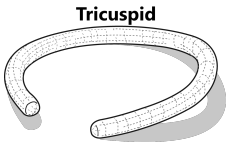


Figure 2: View From Atrium

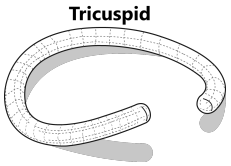


Figure 3: Reverse Side

Figure 4

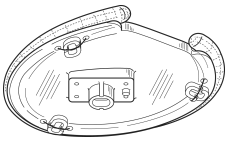


Figure 5

Figure 6

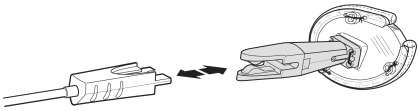


Figure 7

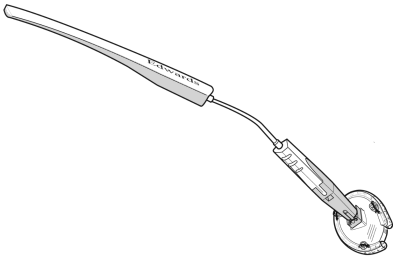


Figure 8

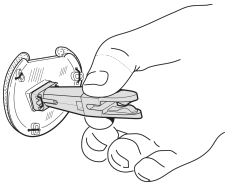


Figure 9

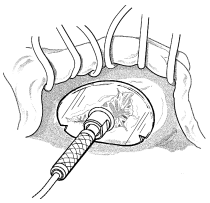


Figure 10

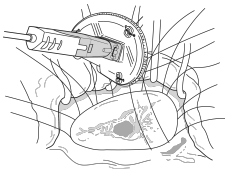


Figure 11

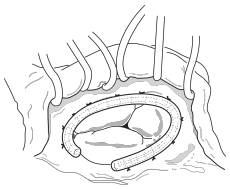


Figure 12

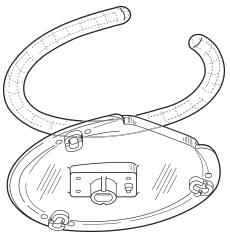


Figure 13

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
10052677001 A / DOC-0198262 A

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

Telephone 949.250.2500
800.424.3278
FAX 949.250.2525

Web IFU