Edwards MC3 Tricuspid Annuloplasty Ring
Model 4900 with Template/Lanyard for Valvuloplasty

For Single Use Only

1.0 Concept/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, resulting in a measured annuloplasty.

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 to allow the annulus to move with the dynamic motion of the valve while providing support against dilatation (Figure 4).

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 quick and efficient connecting and disconnecting of the two components.

2.0 MRI Compatibility

Testing of this device in a magnetic field of 1.5, 3.0 and 8.0 tesla has shown that this device is safe and compatible during MRI (magnetic resonance imaging) procedures.

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 Diagnoses for Valve Reconstruction

The primary diagnosis for this technique is acquired tricuspid insufficiency, whether functional or organic. Indications for tricuspid repair are based on the evolution of the insufficiency as diagnosed by angiography or echocardiography during preoperative medical treatment. In patients with an irreversible tricuspid insufficiency, the condition should be corrected. Completely reversible insufficiencies should not, however, be corrected by ring annuloplasty.

Partially reversible tricuspid insufficiencies should be explored and the orifice measured using the appropriate sizers. If the area of the orifice is significantly larger than the size 32 sizer in women, size 34 in men, or if organic lesions of the leaflets are present, the insufficiency should be corrected.

Combined tricuspid insufficiency and stenosis should be corrected by a triple commissurotomy and valvular remodeling. Severe organic lesions of the posterior leaflet should be treated by two incisions, one at the anteroseptal commissure, the other at the posterior leaflet.

5.0 Valvuloplasty Techniques

Clinical results with the use of prosthetic rings in general 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**).

The Edwards MC3 Tricuspid annuloplasty ring is intended to offer the following advantages:

1. A measured correction of dilatation, conserving the optimal orifice area.

2. A measured reduction of the dilated annulus, preserving the normal annular function.
3. Correction based on the precise measurement of the valvular apparatus, providing a predictable result.
4. Prevention of recurrent dilatation.
5. The opening is at the anteroseptal commissure, thus avoiding sutures in the area of the bundle of His.

Additionally:

1. The small size and low profile of the annuloplasty ring minimize the exposure of foreign material in the atrium and may lead to a reduced thromboembolic incidence.

6.0 Contraindications

Use of the Edwards MC3 Tricuspid annuloplasty ring is contraindicated in the following circumstances:

1. In children where future growth may compromise the effective valve area.
2. In patients with active bacterial endocarditis when the use of prosthetic materials, including the Edwards MC3 Tricuspid annuloplasty ring, may be contraindicated.

7.0 Warnings

7.1 For Single Patient Use Only

The decision to use the Edwards MC3 Tricuspid annuloplasty ring must ultimately be made by the physician on an individual basis after carefully evaluating and discussing with the patient 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 the annuloplasty ring who are undergoing dental or other surgical procedures should receive prophylactic antibiotic therapy to minimize the possibility of systemic infection.

8.0 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 the cloth during removal of the tag.

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

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

Sizing the annulus properly is essential. Use only the appropriate tricuspid sizer provided by Edwards Lifesciences LLC to size the annulus.

Do not attempt to use the template as a sizer.

9.0 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; thrombosis; 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; complications related to prolonged bypass, aortic cross clamping, and inadequate myocardial protection; partial or complete dislodgment 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; tearing of the cloth covering with the use of cutting needles; bleeding diatheses related to the use of anticoagulation therapy; and local and/or systemic infection.

10.0 Instructions for Use

10.1 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).

10.2 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.

10.3 Tricuspid Position

Measurement and Selection of the Appropriate Annuloplasty Ring

Because the intention of the technique of valvular remodeling 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.

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.

11.0 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 rapid 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 (see **Resterilization Instructions**).

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

12.0 Annuloplasty Ring with Template/ Lanyard

12.1 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

12.2 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. If a tray is either opened or compromised, but the annuloplasty device is not used, soiled, dropped or damaged, the system may be resterilized (See **Resterilization Instructions**).

12.3 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.

12.4 Resterilization Instructions

The annuloplasty device may be resterilized no more than five times before the date stamped on the package if the device is not used, soiled, dropped or damaged. The annuloplasty device cannot be used after the date stamped on the package. When resterilization is contemplated, each institution should establish sterilization procedures that include biological indicators to establish the efficacy of their procedures. It is recommended that the annuloplasty device be resterilized no more than five times.

The annuloplasty device must be removed from its packaging before sterilization. The template and handle must not be connected when resterilizing.

It is recommended that a suitable outer wrap be used if storage is contemplated.

The following conditions are recommended for resterilization of the annuloplasty device:

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

Gamma radiation should never be used for sterilization of the Edwards MC3 Tricuspid annuloplasty ring, as this may result in deterioration of the annuloplasty ring.

13.0 Accessories

13.1 Specifications

Annuloplasty Ring Handle Model 1150

13.2 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.

13.3 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.

13.4 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.

13.5 Sterilization Instructions

Sizers and sizer handles must be disassembled before resterilization. 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-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.

14.0 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.

15.0 Recovered Clinical Implants

Edwards is extremely interested in obtaining recovered clinical specimens of 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 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.

16.0 Technical Assistance

For technical assistance, please call Edwards Technical Support at the following telephone numbers:

Inside the U.S. and Canada
(24 hours): 800.822.9837
Outside the U.S. and Canada
(24 hours): 949.250.2222

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

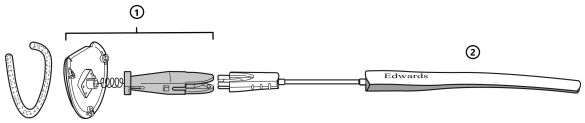
Prices and model availability are subject to change without notice.

This product is manufactured and sold under one or more of the following US patent(s): US Patent No. 6,749,630; 6,908,482 and 7,367,991; and corresponding foreign patents.

17.0 References

1. Carpentier, A. Cardiac Valve Surgery - The French Correction. *J. Thorac. Cardiovasc. Surg*., 86:323-337, 1983.
2. Cosgrove, D.M. et al. Initial Experience with the Cosgrove-Edwards Annuloplasty System. *Ann. Thorac. Surg*., 60:499-504, 1995.
3. 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.
4. 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



1. Template/Lanyard Assembly
2. Handle

Figure 1

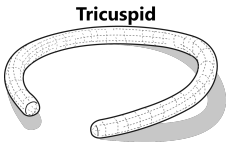


Figure 2: View From Atrium

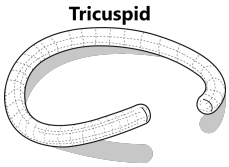


Figure 3: Reverse Side

Figure 4

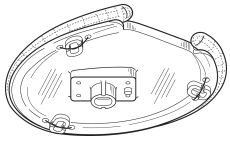


Figure 5

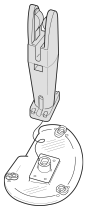


Figure 6

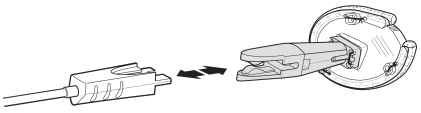


Figure 7

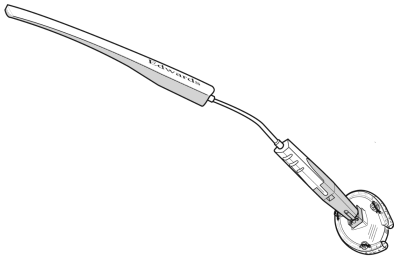


Figure 8

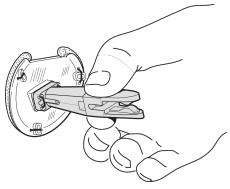


Figure 9

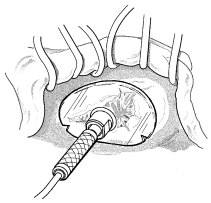


Figure 10

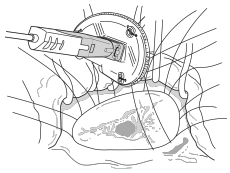


Figure 11

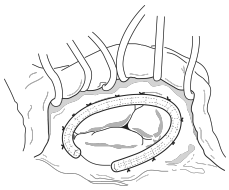


Figure 12

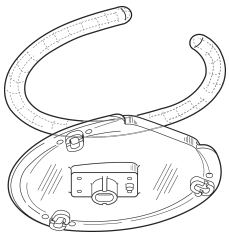


Figure 13

Symbol Legend

	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	Authorized representative in the European Community
	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*

07/21
10038358001 A

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

Telephone 949.250.2500
800.424.3278
FAX 949.250.2525

Web IFU