Cosgrove-Edwards Annuloplasty System
Model 4600 with Template/Lanyard for Valvuloplasty

For Single Use Only

For figures 1 through 13 please refer to pages 6 through 7.

1.0 Concept/Description

The Cosgrove-Edwards annuloplasty system, Model 4600, consists of two primary components: the implantable flexible annuloplasty band and the template/lanyard assembly (or holder). An optional handle, Model 1150, is available separately (Figure 1).

The implantable annuloplasty band is composed of a silicone rubber strip compounded with barium sulfate to enable radiographic visualization. This silicone rubber strip is covered with polyester velour cloth, which is sewn together with a single seam.

The Cosgrove-Edwards annuloplasty system can be used in mitral and tricuspid valve repairs. For use in the mitral position, the size of the annuloplasty band is determined by the dimensions of the mitral annulus. The Cosgrove-Edwards annuloplasty band is available in lengths long enough to extend from fibrous trigone to fibrous trigone based on the long diameter of the mitral annulus.

For use in the tricuspid position, the size of the annuloplasty band is determined by the dimensions of the anterior and posterior leaflets. The Cosgrove-Edwards annuloplasty band is available in lengths long enough to extend from the anteroseptal commissure to the posteroseptal commissure supporting the anterior and posterior portions of the tricuspid annulus.

The annuloplasty band, although flexible, requires rigidity during implantation, which is provided by an integral template. The template serves as a stent during the plication of the annulus, resulting in a measured annuloplasty.

A feature of the Cosgrove-Edwards annuloplasty system 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 Band/Template/ Lanyard Assembly**).

After implantation, this rigid template is removed to allow the annuli to move with the dynamic motions of the valves while providing support against dilatation (See Figure 2 on page 6).

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

2.0 Indications

The Cosgrove-Edwards annuloplasty system, Model 4600, is intended for use in patients to correct annular dilatation, increase leaflet coaptation, reinforce annular suture lines, and prevent further dilatation of the annulus.

3.0 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 Cosgrove-Edwards annuloplasty system 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.

Additionally:

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

4.0 Contraindications

Use of the Cosgrove-Edwards annuloplasty system 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 Cosgrove-Edwards annuloplasty band, may be contraindicated.

5.0 Warnings

5.1 For Single Patient Use Only

The decision to use the Cosgrove-Edwards annuloplasty system 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 band who are undergoing dental or other surgical procedures should receive prophylactic antibiotic therapy to minimize the possibility of systemic infection.

6.0 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 band by a suture. This tag should not be detached from the annuloplasty band 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 band, suture needles with cutting edges and metal forceps must not be used during insertion.

To ensure the sterility and integrity of the annuloplasty system, the annuloplasty system 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 sizers (mitral or tricuspid, according to the implant position) provided by Edwards Lifesciences LLC to size the annulus.

Do not attempt to use the template as a sizer.

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 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 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; systolic anterior motion and left ventricular outflow tract obstruction whenever a large posterior leaflet is present; and local and/or systemic infection.

8.0 Instructions for Use

8.1 Annuloplasty Band/Template/Lanyard Assembly

The annuloplasty band is provided mounted to a disposable template. The annuloplasty band is mounted on the template with three white retaining sutures in order to provide visualization against the template (See Figure 3 on page 6).

A unique template/lanyard assembly is provided to facilitate implantation of the annuloplasty band. 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 band assembly. The internal spool of monofilament thread also presents a means of preventing the template from dropping into the left or right ventricle during the removal process (See Figure 4 on page 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 (See Figure 5 on page 6). The middle section of the handle is malleable, allowing the handle to be adjusted

(bent) in a configuration convenient for use (See Figure 6 on page 6). The template assembly and handle may remain attached until the annuloplasty band is in place or, prior to lowering the annuloplasty band 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 (See Figure 5 on page 6). The surgeon may then position the annuloplasty band by holding the post at the connection point (See Figure 7 on page 6). 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 Mitral Position

Measurement and Selection of the Appropriate Annuloplasty System

Because the technique of annular plication is intended to restore a physiological orifice, measurement and annuloplasty band selection is based on the measurement of the surface area of the anterior leaflet when it is unfurled so that the entire surface area may be visualized (See Figure 8 on page 6). To facilitate this measurement, the chordae tendineae may be placed on tension, thus spreading the leaflet. The correct size of annuloplasty band is determined when the surface area of the sizer closely corresponds to the surface area of the anterior leaflet. (See Figure 9 on page 6). The most commonly used sizes are 30 mm and 32 mm in women, and 32 mm and 34 mm in men.

Insertion of the Prosthesis

Insertion of the prosthesis in the mitral position can be done by interrupted horizontal sutures in the fibrous mitral annulus 2 mm from the leaflet hinge. Approximately 6 to 8 sutures are usually required.

To facilitate exposure of the mitral annulus for passing the suture, the leaflet should be gently moved away from the suture area.

8.4 Tricuspid Position

Measurement and Selection of the Appropriate Annuloplasty System

The technique of annular plication is intended to restore a physiological orifice. Measurement and annuloplasty band selection is based on the measurement of the septal leaflet attachment by using sizers. The marks on the sizer should equal the extremes of attachment at the septal leaflet (See Figure 10 on page 7).

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 placed on tension, thus spreading the leaflet.

Insertion of the Prosthesis

Insertion of the prosthesis in the tricuspid position can be done by interrupted horizontal mattress sutures in the fibrous tricuspid annulus 2 mm from the leaflet hinge. Sutures are placed beginning at the commissure between the septal and posterior leaflets and proceeding anteriorly to the commissure between the septal and anterior leaflets (See Figure 11 on page 7).

To facilitate exposure of the tricuspid annulus for passing the suture, the leaflets should be gently moved away from the suture area.

It is essential that a precise relationship of the anterior and posterior leaflets and the annuloplasty band be maintained (See Figure 12 on page 7).

9.0 Annuloplasty Band Template Removal – Mitral/Tricuspid Indications

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 band from the template (See Figure 13 on page 7). 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 band, the template is to be discarded. The handle may be reused (see **Resterilization Instructions**).

The template must be removed from the band. 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 mitral and tricuspid valve repairs, intraoperative echo has been instrumental in assessing valvular competency and the quality of repair, including the absence of systolic anterior motion (S.A.M.).

Care in the measurement of the orifice, annuloplasty band 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 band 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 band and replace the diseased valve with a prosthetic valve during the same procedure.

10.0 Annuloplasty Band with Template/ Lanyard

Specifications

Cosgrove-Edwards annuloplasty band with Template/ Lanyard for mitral and tricuspid valve repairs, Model 4600

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

10.1 How Supplied

The Cosgrove-Edwards annuloplasty band 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**).

10.2 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.

10.3 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 Cosgrove-Edwards annuloplasty system, as this may result in deterioration of the annuloplasty band.

11.0 Accessories

Specifications

Annuloplasty System Handle Model 1150

Sizers/Handles (Push Fit Connection)

Push Fit Mitral Sizers Model 1164 Sizes: M26 - M38

Push Fit Tricuspid Sizers Model 1165 Sizes: T26 - T38

Push Fit Sizer Handle Model 1146

Sizers/Handles (Threaded Connection)

Threaded Mitral Sizers Model 1174 Sizes: M26 - M38

Threaded Tricuspid Sizers Model 1175 Sizes: T26 - T38

Threaded Sizer Handle Model 1111

Sizer/Handle Tray - Mitral Model TRAY1174

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 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.

11.3 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.

12.0 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.

13.0 Recovered Clinical Implants

Edwards is extremely interested in obtaining recovered clinical specimens of annuloplasty bands 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 bands. The annuloplasty bands 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 bands are available upon request.

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.

14.0 References

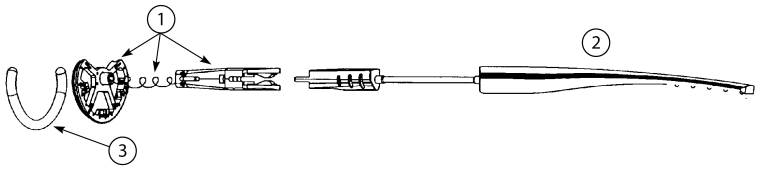
1. Carpentier, A. Cardiac Valve Surgery - The French Correction. *J. Thorac. Cardiovasc. Surg*., 86:323-337, 1983.

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
3. Annuloplasty Band

Figure 1

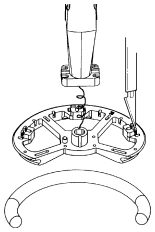
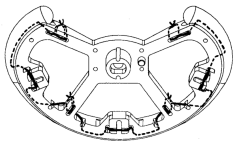


Figure 2



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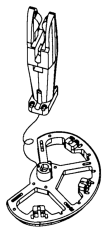

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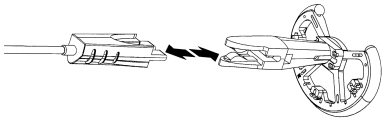

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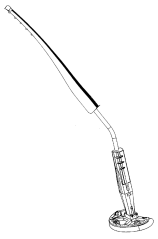


Figure 6

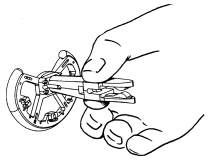
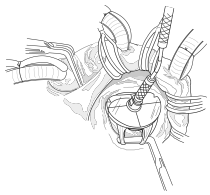


Figure 7

Figure 8



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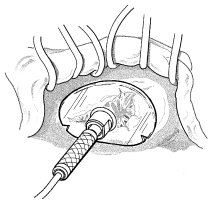
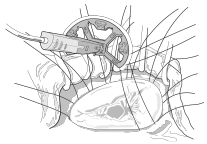


Figure 10



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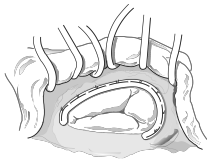


Figure 12

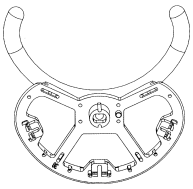
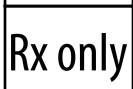


Figure 13

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 Safe
	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
	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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