Cosgrove-Edwards Annuloplasty System with Template/Lanyard for Valvuloplasty

Model 4600

For Single Use Only

1.0 Product 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.

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 annulus to move with the dynamic motions of the valves (Figure 2).

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

2.0 Indications

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 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

4.0 Warnings

4.1 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 band to conform to a specific annular anatomy, as it could damage the band. If the band is not suitably sized for the annulus, select a larger or smaller band.

Do not cut any threads on the ring. Cutting these threads can create loose threads with the potential for thromboembolism or hemolysis.

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.

Remove the holder from the band after the band is implanted. Implantation of the holder with the band 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.

This device was manufactured without latex but may have been produced in a latex-containing environment.

Components of the Model 4600 include polyester, silicone, and barium sulphate. 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.

5.0 Precautions

A serial number tag is attached to the annuloplasty band 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 band.

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.

Inspect the packaging, ensuring that it has not been opened or damaged. Do not use bands that have been removed from the double trays and dropped, soiled, or possibly damaged.

Gentle handling is required for all implantable bands. To ensure the sterility and integrity of the band, the band 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 band and the annulus. Do not attempt to use holder as a sizer.

Do not use the band after the expiration date on the label.

Do not attempt to use the template as a sizer.

6.0 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 bands. 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/tricuspid regurgitation is a potential complication associated with annuloplasty rings.

Following is a list of complications associated with mitral/tricuspid valve repair and prosthetic band annuloplasty compiled from literature and from reports received through the Edwards complaint handling system.

Procedural and Product Complications:

- residual or recurrent mitral/tricuspid regurgitation;
- stenosis;
- thrombosis;
- thromboembolism;
- hemolysis;
- heart block;
- low cardiac output, right heart failure;
- recurrence of mitral/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 band from its site of attachment (dehiscence);
- malfunction of the band due to distortion at implant or physical or chemical deterioration of band components;
- fracture of the band components;
- fraying of the cloth or suture material;
- (Mitral only) 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.

7.0 Instructions for Use

7.1 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 (Figure 3).

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 (Figure 4).

7.2 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 5). The middle section of the handle is malleable, allowing the handle to be adjusted (bent) in a

configuration convenient for use (Figure 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 (Figure 5). The surgeon may then position the annuloplasty band by holding the post at the connection point (Figure 7). 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.

7.3 Mitral Position

Measurement and Selection of the Appropriate Annuloplasty System

Because the technique 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 (Figure 8). 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 (Figure 9).

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.

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.

7.4 Tricuspid Position

Measurement and Selection of the Appropriate Annuloplasty System

The technique 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 (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 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.

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. Approximately 6 to 8 sutures are required. 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 (Figure 11).

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 (Figure 12).

8.0 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 removal of the annuloplasty band 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 band, the template is to be discarded. The handle may be reused.

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 should consider alternative treatment options.

9.0 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

9.1 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.

9.2 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.

10.0 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.

10.1 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.

10.2 Cleaning and Sterilization Instructions

For 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 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.

11.2 Recovered Clinical Implants

Edwards is extremely interested in obtaining recovered clinical specimens of annuloplasty bands for analysis. 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.

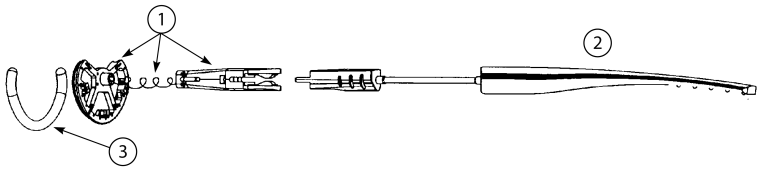
12.0 Physician Training

The techniques for implanting this band are similar to those used for the placement of any annuloplasty band. No additional training is required to implant the Cosgrove-Edwards annuloplasty band, model 4600. It is the surgeon's decision when and if to repair a mitral/tricuspid valve.

13.0 References

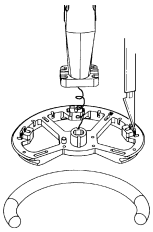
1. Carpentier A., Adams D. A., Filsoufi F. Carpentier's Reconstructive Valve Surgery. Maryland Heights, MO: Saunders Elsevier, 2010.
2. Guidelines on the management of valvular heart disease (version 2012). The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (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
3. Annuloplasty Band

Figure 1



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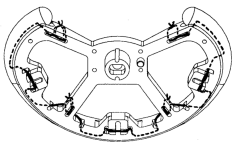
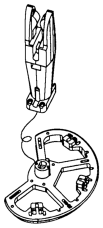


Figure 3



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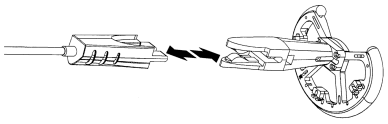
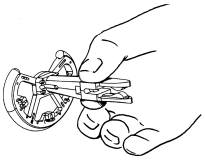


Figure 5

Figure 6



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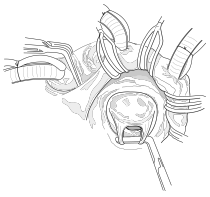

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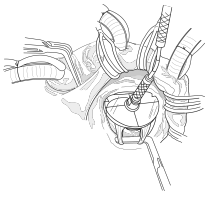

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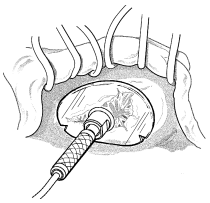

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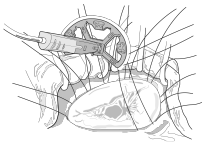

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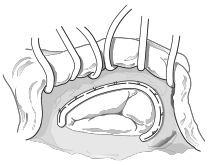

Figure 12

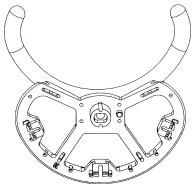

Figure 13

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 Safe

	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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