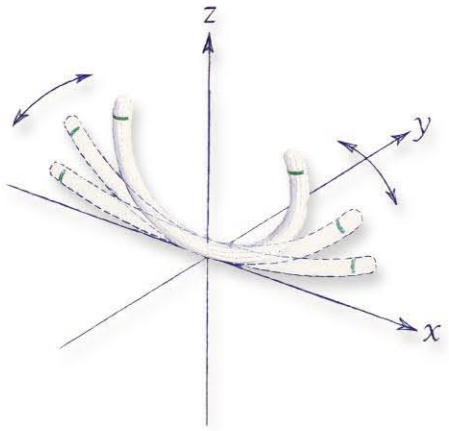
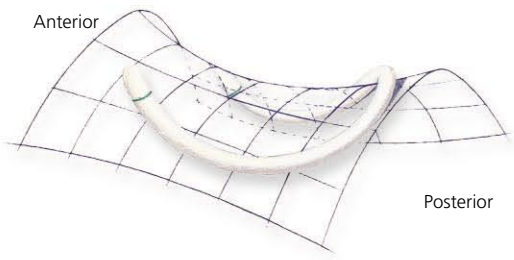
Cosgrove-Edwards Annuloplasty System





FEATURE: System Concept

BENEFIT: Template Handle

- Provides a measured plication of the annulus
- Allows for easy release of band via suture cuts
- Increases ease-of-use and operative efficiency
- Holds flexible band shape during implantation
- Allows for release of the lanyard, enabling removal of the handle from surgical field

FEATURE: Universally Flexible Band

BENEFIT:

- Flexible band allows for natural annulus sphincter movement during the cardiac cycle
- Adapts to three-dimensional contour of the annulus while providing support against dilatation

FEATURE: Anatomic Compatibility

BENEFIT:

- Reinforcement band enables preservation of native saddle shape and natural function
- Polyester velour cloth band encourages host tissue ingrowth
- Multiple band lengths accommodate different posterior leaflet dimensions

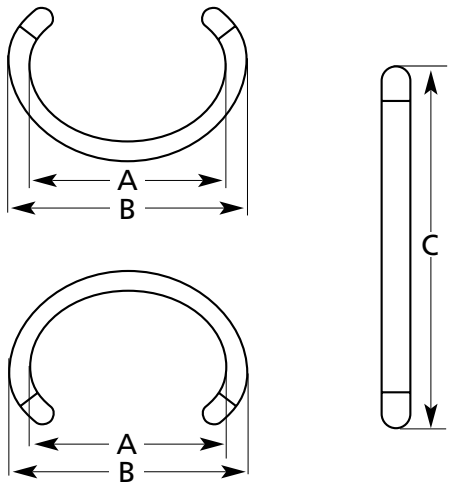
For use in both Mitral and Tricuspid positions

Edwards
LIFESCIENCES

Cosgrove-Edwards Annuloplasty System

The Cosgrove-Edwards Annuloplasty Band, from Edwards Lifesciences LLC, is made of barium sulfate impregnated silicone rubber covered by a polyester velour cloth.

The band is provided on a template, sterile and nonpyrogenic in double plastic trays. For resterilization by steam, the band must be removed from the original package and transferred to a suitable container. The optional, reusable handle is provided non-sterile and may be sterilized by steam.



To further enhance blood compatibility when using valve repair implantables, Edwards offers a line of annuloplasty devices with the renowned Duraflo Treatment, a heparin bonded treatment. Duraflo Treatment is known for its ability to reduce unfavorable responses to foreign materials when employed on short-term cardiopulmonary bypass devices. In a short-term canine shunt study conducted by Edwards, polyester annuloplasty cloth with Duraflo Treatment showed reduced platelet aggregation when compared to untreated polyester. These data also suggest that the effect of Duraflo Treatment on polyester cloth continues after exposure to systemic heparinization and protamine reversal. In an endocardial tissue study in sheep, gross observations of tissue ingrowth indicated no significant difference between annuloplasty devices with Duraflo Treatment versus untreated devices. Clinical studies have demonstrated that Duraflo Treatment improves blood compatibility on non-biological surfaces when applied to short-term cardiopulmonary-type devices. However, there are no clinical data available which evaluate the long-term effectiveness of Duraflo Treatment in reducing thrombus formation.

Model Description	Model Number
Cosgrove-Edwards Annuloplasty System (mitral/tricuspid)	4600
Cosgrove-Edwards Annuloplasty System with Duraflo Treatment	4625
Handle	1150
Mitral Sizers	1174
Tricuspid Sizers	1175
Handle for Sizers (reusable)	1111
Handle for Sizers (single use)	1126

Specifications

Ring size	26mm	28mm	30mm	32mm	34mm	36mm	38mm
Inner band diameter (A)	25.9mm	28.0mm	30.0mm	31.9mm	34.0mm	35.9mm	37.9mm
Outer band diameter (B)	33.6mm	35.6mm	37.6mm	39.6mm	41.6mm	43.6mm	45.6mm
Total length of band (C)	57.9mm	62.0mm	66.3mm	70.4mm	74.7mm	78.7mm	83.1mm

Indications
The Cosgrove-Edwards Annuloplasty System, Models 4600 and 4625, is intended for use in patients to correct annular dilatation, increase leaflet coaptation, reinforce annular suture lines, and prevent further dilatation of the annulus.

Contraindications
Use of the Cosgrove-Edwards Annuloplasty System is contraindicated in the following circumstances:
1. In children where future growth may compromise 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.

Warnings
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 reinforcement band who are undergoing dental procedures should receive prophylactic antibiotic therapy to minimize the possibility of systemic infection.

Precautions
Before clinical application, surgeons should become familiar, by appropriate training, with the surgical technique and its variations.
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 to size the annulus. Do not attempt to use the template as a sizer.

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 dislodgement 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 the 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.
See package insert for full prescribing information.

CE
Certified according to European MDD

This product is covered by U.S. and foreign patents including the following: 5,041,130

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

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