Carpentier-Edwards Classic Annuloplasty Rings

Carpentier-Edwards Classic Annuloplasty Rings have been the repair device of choice for thousands of surgeons for more than 20 years. The rings are designed to restore the anatomical size and shape of the valve and to help prevent recurrent dilatation.

FEATURE	BENEFIT
Annuloplasty Ring Construction • Solid Titanium Core	• Provides strength and durability • Visible on x-ray
Sewing Ring Construction • Polyester Knit Fabric • Colored Thread and Commissure Markers	• Facilitates tissue ingrowth, helps to anchor ring and minimizes the risk of dehiscence • Indicates side of the ring to place against patient's annulus for easier suture placement • Indicates location of the commissures
Mitral Model 4400 • Mitral Kidney-shaped Ring	• Remodels the annulus by providing a 3:4 ratio between the anteroposterier and transverse diameters of a normal mitral valve for optimal hemodynamic performance
Tricuspid Model 4500 • Tricuspid Oval Ring	• Conforms to the configuration of the normal tricuspid orifice • Opening in the anteroseptal commissure allows surgeon to avoid sutures in the area of the bundle of His

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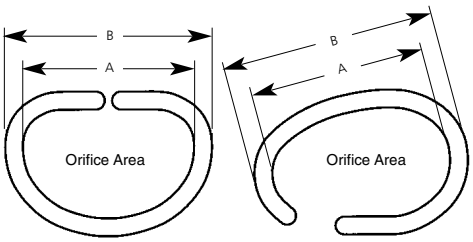
Carpentier-Edwards Classic Annuloplasty Rings, from Edwards Lifesciences LLC, are made of titanium alloy and have a sewing ring that consists of a layer of silicone rubber covered by a polyester knit fabric. The rings are provided sterile and nonpyrogenic in double-wrapped, clear trays. For resterilization by steam, the rings must be removed from the original package and transferred to a suitable container.

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 material 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
Carpentier-Edwards Classic Mitral Annuloplasty Ring	4400
Carpentier-Edwards Classic Mitral Annuloplasty Ring with Duraflo Treatment	4425
Carpentier-Edwards Classic Tricuspid Annuloplasty Ring	4500
Carpentier-Edwards Classic Tricuspid Annuloplasty Ring with Duraflo Treatment	4525
Mitral Sizers	1174
Tricsupid Sizers	1175
Handle for Sizers (reusable)	1111
Handle for Sizers (single use)	1126

Mitral Specifications

Ring Size	26mm	28mm	30mm	32mm	34mm	36mm	38mm	40mm
Inner ring diameter (A)	24.3mm	26.3mm	28.3mm	30.3mm	32.3mm	34.3mm	36.3mm	38.3mm
Outer ring diameter (B)	31.2mm	33.2mm	35.2mm	37.2mm	39.2mm	41.2mm	43.4mm	45.4mm
Orifice Area	288mm^2	339mm^2	395mm^2	455mm^2	519mm^2	586mm^2	659mm^2	736mm^2

Tricuspid Specifications

Ring Size	26mm	28mm	30mm	32mm	34mm	36mm
Inner ring diameter (A)	24.3mm	26.3mm	28.3mm	30.3mm	32.3mm	34.3mm
Outer ring diameter (B)	31.2mm	33.2mm	35.2mm	37.2mm	39.2mm	41.2mm
Orifice Area	310mm^2	364mm^2	423mm^2	486mm ^{2}	553mm^2	626mm^2

Indications

The decision to undertake valvuloplasty can be made only after visual analysis of the lesion present. The most favorable conditions for valvuloplasty using an annuloplasty ring are a combination of the distended natural valve ring associated with supple valve cusps and normal chordae tendineae.

Mitral

The remodeling valvuloplasty technique with a prosthetic ring may be used in all acquired or congenital mitral insufficiencies with dilatation and deformation of the fibrous mitral annulus.

For Type I mitral insufficiencies with no subvalvular lesions and normal valvular movements, this ring technique used alone is sufficient. However, the ring technique must be associated with mitral valvuloplasty repair in Type II insufficiencies with a prolapsed valve due to elongation or rupture of the chordae tendineae and in Type III insufficiencies with limitation of valvular movements due to fusion of the commissures or chordae tendineae, or chordal hypertrophy.

Tricuspid

The primary indication 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 and dye dilution curves 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 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.

Contraindications

Use of the Carpentier-Edwards Classic Annuloplasty Rings is contraindicated in the following circumstances:

1. Severe organic lesions with retracted chordae
2. Congenital malformations with lack of valvular tissue
3. Large valvular calcifications
4. Evolving bacterial endocarditis

Warnings

For Single Patient Use Only

The decision to use an annuloplasty ring must ultimately made by the physician on an individual basis after carefully evaluating 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 in of the exposed cloth and sutures.

Recipients of annuloplasty rings who are undergoing dental procedures should receive prophylactic antibiotic therapy to minimize the possibility of systemic infection.

Do not attempt to deform or otherwise alter the configuration of the annuloplasty ring to conform to a specific annular anatomy, as this could damage the ring. If the ring is not suitably sized for the annulus, a larger or smaller ring should be chosen.

The double-packaged container in which Carpentier-Edwards Classic Annuloplasty Rings are provided is not suitable for autoclave resterilization procedures. If resterilization is necessary, the rings should be removed and transferred to a suitable container.

Precautions

Before clinical application, surgeons should become familiar, by appropriate training, with the surgical technique and its variations. In addition to the guidelines provided, it is recommended that references on the subject be reviewed.

A serial number tag is attached to the prosthesis by a suture. This tag should not be detached from the prosthesis until implant is imminent. Care should be exercised to avoid cutting or tearing of the cloth during removal of the tag.

To avoid damage to the fabric covering the ring, suture needles with cutting edges and metal forceps must not be used during insertion. For ease of orientation, the sewing ring is marked with a colored thread. This side of the ring must lie against the valve annulus.

Complications

A full explanation of the benefits and risks should be given to each prospective patient before surgery. Serious complications, sometimes leading to death, have been associated with the use of annuloplasty 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 advised so that prosthesis-related complications can be diagnosed and properly managed to minimize danger to the patient.

Complications associated with annuloplasty 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, 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 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 dislodgment of the ring from its site of attachment; 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 anticoagulant therapy; and systolic anterior motion (S.A.M.) and left ventricular outflow tract obstruction (L.V.O.T.O) whenever a large posterior leaflet is present.

See package insert for full prescribing information.

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Certified according to European MDD

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

This product is manufactured and sold under one or more of the following U.S. Patents: 3,656,185; 4,055,861

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Edwards Lifesciences

Edwards Lifesciences LLC · One Edwards Way · Irvine, CA 92614 USA · 949.250.2500 · 800.424.3278 · www.edwards.com
Edwards Lifesciences (Canada) Inc. · 1290 Central Pkwy West, Suite 300 · Mississauga, Ontario · Canada L5C 4R3 · Phone 905.566.4220 · 800.268.3993
Edwards Lifesciences S.A. · Ch. du Glapin 6 · 1162 Saint-Prex · Switzerland · Phone 41.21.823.4300
Edwards Lifesciences Japan · 2-8 Rokubancho · Chiyoda-ku, Tokyo 102-0085 · Japan · Phone 81.3.5213.5700