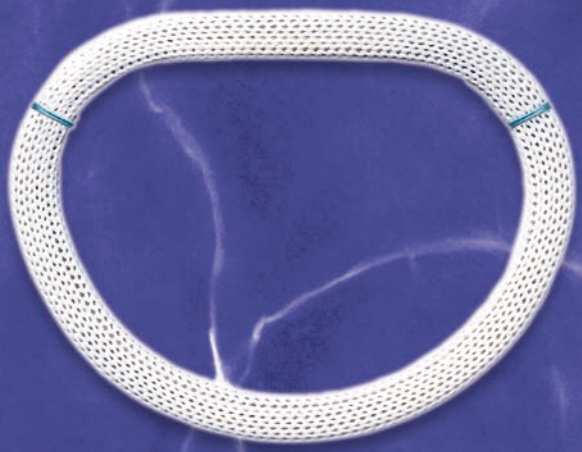
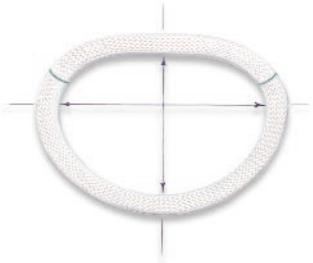
Carpentier-Edwards Physio Annuloplasty Ring





Remodeling

- Preserves natural 3:4 ratio between the anteroposterior diameter and transverse diameter during systole
- Restores anatomical size & shape to provide optimal orifice area

Progressive Posterior Flexibility

- Variable flexibility is created by the movement of Elgiloy* bands separated by plastic bands
- Allows for physiologic contractility of the mitral valve annulus during systole
- Minimizes stresses on sutures

Anatomical Conformance

- Kidney shaped ring conforms to the configuration of the normal mitral annulus
- Anterior saddle shape adapts to aortic root and conforms to annulus' anterior fibrous segment
- Increased anteroposterior dimension better accommodates requirements of degenerative and ischemic valvular repair

Enhanced Ease of Use - Handle/Holder

- Increases ease-of-use and operative efficiency
- Assists in visual orientation for ring placement
- Stabilizes ring during suturing
- Allows for individualized holding preferences

Edwards
LIFESCIENCES

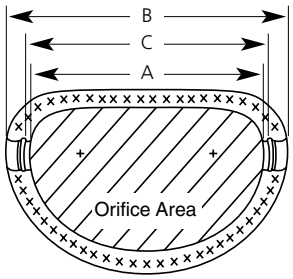
* Elgiloy Limited Partnership

Carpentier-Edwards Physio Annuloplasty Ring

The Carpentier-Edwards Physio Annuloplasty Ring, from Edwards Lifesciences LLC, is made of layers of Elgiloy and plastic strips and has a sewing ring margin that consists of a layer of silicone rubber covered by a polyester knit fabric.

The rings are provided on holders, sterile and nonpyrogenic in plastic trays. For resterilization by steam, the rings must be removed from the original package and transferred to a suitable container. The 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
Carpentier-Edwards Physio Mitral Annuloplasty Ring	4450
Carpentier-Edwards Physio Mitral Annuloplasty Ring with Duraflo Treatment	4475
Handle	1150
Mitral Sizers	1174
Handle for Sizers (reusable)	1111
Handle for Sizers (single use)	1126

Specifications

Ring Size	24mm	26mm	28mm	30mm	32mm	34mm	36mm	38mm	40mm
Inner ring diameter (A)	22.9mm	24.9mm	26.9mm	28.9mm	30.9mm	32.9mm	34.8mm	36.8mm	38.7mm
Outer ring diameter (B)	28.7mm	30.7mm	32.9mm	34.9mm	37.1mm	39.1mm	41.2mm	43.2mm	45.3mm
Inner Elgiloy Band diameter (C)	24mm	26mm	28mm	30mm	32mm	34mm	36mm	38mm	40mm
Orifice Area (mm^2)	274	325	380	440	504	572	645	722	804

Indications

The Carpentier-Edwards Physio Annuloplasty Ring is intended for the correction of mitral valve insufficiency, or mixed mitral insufficiency and stenosis, where treatment does not necessitate a replacement of the natural mitral valve.

The Carpentier-Edwards Physio Annuloplasty Ring is intended to meet the challenges of modern valvuloplasty by maintaining the physiologic annular shape and motion. The annuloplasty ring is designed to follow the functional changes which occur during the cardiac cycle, thereby maintaining coaptation and valve integrity in systole while permitting good hemodynamics in diastole.

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

The remodeling annuloplasty technique with a Carpentier-Edwards Physio Annuloplasty Ring, may be used in all acquired or congenital mitral insufficiencies with dilatation and deformation of the fibrous mitral annulus, with the exception of severe congenital malformations (e.g. AV canal or hypoplastic commissures), or severe degenerative valvular diseases where there is considerable excess tissue.

For Type I mitral insufficiencies with no subvalvular lesions and normal valvular movements, this ring technique used alone is sufficient. However, this 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 or papillary muscle and in Type III insufficiencies with limitation of valvular movements due to fusion of the commissures or chordae, or chordal hypertrophy.

Contraindications

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 be 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 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.

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 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 ring, suture needles with cutting edges and metal forceps must not be used during insertion.

Sutures should be placed no more than 1.5mm away from the external diameter of the sewing ring.

For ease of orientation, the sewing ring is marked with a colored thread. The side of the ring with the colored thread around the circumference always lies against the valve annulus.

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

Sizing the annulus properly is essential. Use only the appropriate sizing obturators provided by Edwards to size the annulus. Do not attempt to use ring holder as a sizing obturator.

The annuloplasty ring must be removed from the holder prior to implantation. Implantation of the holder can cause patient injury or death. In the event that a holder needs to be located within the surgical site, its presence can be detected under x-ray.

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 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 ring components; fracture of the ring components; tearing of the cloth covering with the use of cutting needles; fraying of the suture material and eventual suture breakage upon incorrect placement of the sutures into the ring; bleeding diatheses related to the use of anticoagulation therapy; systolic anterior motion (S.A.M.) and left ventricular outflow tract obstruction (L.V.O.T.O.) 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 manufactured and sold under one or more of the following U.S. Patents: 5,104,407

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

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