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: Annuloplasty Ring Construction**
- Solid Titanium Core

**BENEFIT:**
- Provides strength and durability
- Visible on x-ray

**FEATURE: Sewing Ring Construction**
- Polyester Knit Fabric
- Colored Thread and Commissure Markers

**BENEFIT:**
- 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

**FEATURE: Mitral Model 4400**
- Mitral Kidney-shaped Ring

**BENEFIT:**
- Remodels the annulus by providing a 3:4 ratio between the anteroposterior and transverse diameters of a normal mitral valve for optimal hemodynamic performance

**FEATURE: Tricuspid Model 4500**
- Tricuspid Oval Ring

**BENEFIT:**
- 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
Carpentier-Edwards Classic Annuloplasty Rings

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 implants, 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.

### Mitral Specifications

<table>
<thead>
<tr>
<th>Ring Size</th>
<th>26mm</th>
<th>28mm</th>
<th>30mm</th>
<th>32mm</th>
<th>34mm</th>
<th>36mm</th>
<th>38mm</th>
<th>40mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inner ring diameter (A)</td>
<td>24.3mm</td>
<td>26.3mm</td>
<td>28.3mm</td>
<td>30.3mm</td>
<td>32.3mm</td>
<td>34.3mm</td>
<td>36.3mm</td>
<td>38.3mm</td>
</tr>
<tr>
<td>Outer ring diameter (B)</td>
<td>31.2mm</td>
<td>33.2mm</td>
<td>35.2mm</td>
<td>37.2mm</td>
<td>39.2mm</td>
<td>41.2mm</td>
<td>43.4mm</td>
<td>45.4mm</td>
</tr>
<tr>
<td>Orifice Area</td>
<td>288mm²</td>
<td>339mm²</td>
<td>395mm²</td>
<td>455mm²</td>
<td>519mm²</td>
<td>586mm²</td>
<td>659mm²</td>
<td>736mm²</td>
</tr>
</tbody>
</table>

### Tricuspid Specifications

<table>
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<td>37.2mm</td>
<td>39.2mm</td>
<td>41.2mm</td>
</tr>
<tr>
<td>Orifice Area</td>
<td>310mm²</td>
<td>364mm²</td>
<td>423mm²</td>
<td>486mm²</td>
<td>553mm²</td>
<td>626mm²</td>
</tr>
</tbody>
</table>

### 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 distorted natural valve ring associated with supravalvular or annular tissue prolapse. For Type I mitral insufficiencies with no subvalvular lesions and normal valvular function, annuloplasty is sufficient. For Type II mitral insufficiencies, annuloplasty combined with subvalvular procedures is usually necessary. For Type III mitral insufficiencies with limitation of valvular movements due to fusion of the commissures or chordal tissue, chordal hypotrophy, or chordal attachments, the ring technique must be associated with mitral valvuloplasty repair in Type II insufficiencies. For Type III insufficiencies with limitation of valvular movements, this ring technique used alone is sufficient. However, the ring should be chosen so that the ring is not suitably sized for the annulus, a larger or smaller ring should be used.

### Complications

Complications associated with annuloplasty ring valvuloplasty compiled from the literature and from reports received through the complaint handling 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 small caliber tricuspid ring is indicated for the procedure. If restitution is not necessary, the rings should be removed and transferred to a suitable container.

### 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. 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 used. The double-packed 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.