Carpentier-Edwards
PERIMOUNT MAGNA Mitral Pericardial Bioprosthesis
Model 7000TFX

Implantation Manual
This booklet illustrates my technique for mitral valve replacement with the Carpentier-Edwards PERIMOUNT Magna mitral bioprosthesis. The technique is based on sound surgical principles and on extensive personal experience with Carpentier-Edwards PERIMOUNT mitral bioprostheses over many years. This technique is employed by many cardiothoracic surgeons with excellent results. It is my hope that this booklet proves valuable to the cardiac surgical trainee and cardiac surgeons interested in this implant technique.

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Carpentier-Edwards PERIMOUNT Magna Mitral Pericardial Bioprosthesis
Introduction and Product Description
Introduction & Product Description

In 1984 the Carpentier-Edwards PERIMOUNT mitral pericardial bioprosthesis model 6900 was introduced for replacement of the mitral valve. The mitral bioprosthesis stent and leaflet attachment is similar to the Carpentier-Edwards PERIMOUNT aortic bioprosthesis but was bioengineered to withstand the higher closing pressures encountered in the mitral position. A bioprosthesis has distinct advantages over a mechanical prosthesis in that bioprostheses can allow freedom from lifelong anticoagulation, reduced thromboembolism risks, and reduced major bleeding events. Porcine bioprostheses available in the early 1980s had limited long-term durability in the mitral position due to failures from structural valve deterioration (SVD), primarily from leaflet tears and calcification. It was during this time that the PERIMOUNT mitral bioprosthesis was introduced using design based on computer-aided modeling to minimize leaflet stress (Figure 1), bovine pericardium, and improved tissue processing. One of the largest studies (435 patients) on long-term durability of a mitral bioprosthesis has shown excellent results for the PERIMOUNT mitral bioprosthesis, even with a young mean age of patients at 60.7 years. The cumulative incidence of explant due to SVD at 16 years was shown to be 11% in patients with a PERIMOUNT mitral bioprosthesis implanted at age ≥60 years with no SVD failures reported prior to six years (Figure 2).
Introduction and Product Description

Introduced in 2005, the Carpentier-Edwards PERIMOUNT Magna mitral bioprosthesis model 7000TFX (presented in this manual) embodies over 40 years of Edwards innovation in mitral valve replacement and repair. Building on the same stent and leaflet design of model 6900 PERIMOUNT mitral bioprosthesis, the PERIMOUNT Magna mitral bioprosthesis is designed with an asymmetric sewing cuff to maximize mitral annular conformity. Its sewing cuff is widened and has increased flexibility on the posterior aspect for accommodating calcific degenerative processes commonly encountered in that region when replacing a mitral valve. In addition, by reducing the dimension of the effective profile, the stent projection into the ventricle has been minimized to reduce any ventricular outflow tract obstruction or injury to ventricular endocardial surfaces (Figure 3).

Figure 2. PERIMOUNT mitral bioprosthesis, model 6900, cumulative incidence of explant due to SVD.

Figure 3. Profile and inflow views of PERIMOUNT Magna mitral bioprosthesis.
Carpentier-Edwards PERIMOUNT Magna Mitral Pericardial Bioprosthesis

The PERIMOUNT Magna mitral bioprosthesis includes the Carpentier-Edwards ThermaFix process*, the only tissue treatment that confronts both major causes of calcification – critical to achieving the long-term structural integrity necessary to mitigate the effects of SVD.

Edwards has also developed accessories specific for mitral replacement. The handle (model 1117) has the appropriate flexibility and length for mitral procedures. The sizer (model 1177HP) dimensions accurately replicate the stent and cuff diameters of the bioprosthesis and are labeled with the clinically obtained effective orifice area (EOA) to help gauge the expected hemodynamic performance (Figure 4). The accessories can be organized in a tray (model TRAY1177HP) for easy sterilization (Figure 5). All PERIMOUNT mitral bioprostheses include the Tricentrix holder system, which aids in implantability and visualization, reduces the risk of strut capture with suture tie-down, and eases bioprosthesis insertion (Figure 6).

![Figure 4. Sizer set, model 1177HP.](image1)

![Figure 5. Accessory tray, model TRAY1177HP.](image2)

![Figure 6. Tricentrix holder system.](image3)
Preparation
Bioprosthesis Preparation

The PERIMOUNT Magna mitral bioprosthesis requires preparation prior to implantation. To prepare the bioprosthesis for implantation these steps must be followed (Figures 7-18).

**Figure 7.** Insert the handle 1111 or 1117 (reusable) or 1126 (disposable) and turn clockwise until snug fit. Once the handle has been attached, it should not be removed until the bioprosthesis is seated in the annulus.

**Figure 8.** Remove the assembly from the jar.

**Figure 9.** Grasp the plastic sleeve (cage) and rotate the handle clockwise an additional 1/4-turn or until the post reaches the unlock position;

**Figure 10.** then push on the handle until the post snaps into its fully deployed position. This creates the protective tenting structure that reduces the risk for looping a suture around a strut during implantation.

**Figure 11.** Remove the sleeve. The sleeve is removed by pulling away from the rest of the assembly.

**Figure 12.** Remove the clip. The clip is removed by sliding it away from the holder.
Figure 14. Rinse the bioprosthesis two times, one minute each, in separate saline bowls filled with at least 500 ml saline.

Figure 13. The ID tag is used to verify size and serial number and then removed by cutting the attachment thread.

Figures 15 & 16. Check for proper deployment; the holder should be locked. There should be no space between the base of the white post and the holder, and no sliding movement. The green tenting threads will form a protective barrier that reduces the risk of looping a suture around a strut.

Figure 18. and pushing on the handle until the tenting structure is produced and the post snaps into position.

Figure 17. If the surgeon suspects that the holder is not fully deployed when handed the bioprosthesis, deployment can be completed by gently holding the bioprosthesis sewing cuff, unlocking the post (1/4-clockwise turn of the handle),
Technique
**Patient Preparation**

The operation is typically preceded by administration of general anesthesia of narcotic and/or inhalational agents, placement of a urinary catheter, placement of a pulmonary artery catheter for monitoring of pulmonary pressures and cardiac output, and intravenous antibiotics are administered and generally continued for two days.

**Exposure**

Routinely, exposure for mitral valve replacement is achieved via a median sternotomy. The pericardium is opened longitudinally in the midline from the reflection over the aorta to the diaphragm where it is T’ed to the pleural reflections (Figure 19). The pericardial edges are sutured to the sternotomy wound creating a pericardial cradle. The heart is prepared for bypass after systemic heparinization. Cannulation is performed by using two right angle cannulae for venous blood drainage and placing an arterial cannula in the distal ascending aorta. A small cannula is placed in the superior vena cava above the sino-atrial node. The other caval cannula is placed in the right atrium at the junction of the atria and the inferior vena cava. Cardiopulmonary bypass is initiated and flow is set to about 1.5 L/min/m². Adequate decompression of the heart is assured and hypothermia is initiated by cooling to 30-34°C. The myocardium can be protected using antegrade and retrograde cold (4°C) cardioplegia. Using an initial loading dose of antegrade cardioplegia with subsequent retrograde doses every fifteen to twenty minutes is useful to maintain myocardial protection. Retrograde cardioplegia may be more effective as the aortic valve can sometimes distort and become incompetent during retraction of the atrium. Retrograde cardioplegia also protects the ischemic left ventricle in the presence of coronary artery disease and helps in de-airing of the heart and the ascending aorta.
Exposure of the mitral valve is aided by developing Sondergaard’s plane near the inter-atrial groove. This is accomplished by careful cautery dissection of the plane separating the right from the left atrium extending from the junction of the superior vena cava to the junction of the inferior vena cava. The more medial that this dissection can be accomplished allows the left atrial incision to be made close to the atrial septum and greatly aids in the exposure of the mitral valve (Figure 20). Upon opening the left atrium, exposure of the mitral valve is accomplished by retraction of the left atrial wall at the 10-11 o’clock position and inferiorly at the 2-3 o’clock position. Retraction is assisted with the availability of many commercial mitral valve retractors (Figure 21).

**Annular Preparation**

With adequate exposure, identification of the important left atrial structures such as the orifice of the left and right pulmonary veins, left atrial appendage and mitral valve apparatus is accomplished. One should first assess the degree of calcification of the anterior and posterior mitral valve leaflets and annulus. Severe calcification of the leaflets and annulus may lead to significant difficulties in seating the bioprosthesis. As much as possible, debridement of the anterior and posterior annulus should be accomplished. If excessive calcification is encountered along the anterior leaflet and annulus, excision of the anterior mitral valve leaflet leaving a 2-3 mm rim of tissue to bolster pledged sutures may be helpful. If the posterior mitral valve annulus is severely calcified, attempts to debride this tissue can be made but increase the risk of atrial ventricular disruption. In this case, the posterior mitral valve leaflet itself can be utilized as the anchors for the valve sutures. If extensive
debridement is necessary, utilization of an ultrasonic surgical aspirator device or reconstruction of the posterior annulus using bovine pericardium may be necessary.

Beyond the above considerations regarding valve and annular debridement, replacement of the mitral valve preferably involves some form of native leaflet and thus chordal-papillary muscle preservation. Studies have shown improved outcomes in patients with leaflet and chordal-papillary muscle preservation\(^1\). The anterior leaflet can be preserved by partially excising it or folding it against anterior annulus using a polypropylene suture. Preservation of all or some of the posterior leaflet can preserve chordal-papillary support, and in the case of friable or calcified annular tissue, can protect the atrial-ventricular groove from rupture\(^6\). If the anterior mitral valve leaflet is excised to aid in placement of a larger bioprosthesis, in most cases the posterior mitral leaflet with its chordal attachments can be preserved.

If all the native leaflet tissue and subsequent chordal support must be sacrificed, papillary muscle resuspension can still be accomplished. Routinely, a pledgeted 5-0 fluoropolymer suture can be placed in the fibrous head of the anterior-lateral or posterior-medial papillary muscle and brought to the mitral valve annulus. Correct length of the chord is usually aided by measuring it against remaining secondary chordal elements. Anchoring these sutures to the annulus at the 8 o’clock position for the antero-lateral papillary muscle and at the 4 o’clock position for the posterior-medial papillary muscle prevents impingement on the struts or the outflow tract (Figure 22).
Sizing and Bioprosthesi...
**Sizing**

The suturing technique described in this guide for attaching the PERIMOUNT Magna mitral bioprosthesis to the mitral annulus uses pledgeted mattress sutures placed from the ventricle to the atrium with pledgets on the ventricular side, also called a non-evertting technique. This technique may allow the use of a larger size bioprosthesis while improving left ventricular outflow by further reducing ventricular projection of the stent.

When sizing for non-evertting suturing techniques the sizer barrel should comfortably fit in the annulus while the lip of the sizer should be seated on top of the annulus (Figure 23). The dimensions of the sizer barrel match the external stent diameter while the dimensions of the sizer lip match the bioprosthesis sewing cuff, giving an accurate reflection of bioprosthesis fit (Figure 24 a and b).
The sizer lip of model 1177HP is asymmetric in a similar manner to the PERIMOUNT Magna mitral bioprosthesis sewing cuff. The sizer has left ventricular outflow tract (LVOT) markings that match the bioprosthesis. The two black markings (one double and one single) help aid in the sizer orientation and the space between them should be positioned over the LVOT as the bioprosthesis will later be (Figure 25). Over-sizing should be avoided with the PERIMOUNT Magna mitral bioprosthesis as all sizes have excellent hemodynamics and over-sizing increases the risk of stent distortion (Figure 26).

Figure 25. Sizer positioning with the space between the black markers aligned over the LVOT.

Figure 26. Clinical EOA at 1-2 yr post implant cm$^2$.

<table>
<thead>
<tr>
<th>Valve Size</th>
<th>Clinical EOA at 1-2 yr post implant cm$^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 mm</td>
<td>1.8</td>
</tr>
<tr>
<td>27 mm</td>
<td>2.3</td>
</tr>
<tr>
<td>29 mm</td>
<td>2.6</td>
</tr>
<tr>
<td>31 mm</td>
<td>2.6</td>
</tr>
<tr>
<td>33 mm</td>
<td>2.5</td>
</tr>
<tr>
<td>n=</td>
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<tr>
<td>3</td>
<td></td>
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<tr>
<td>40</td>
<td></td>
</tr>
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<td></td>
</tr>
<tr>
<td>27</td>
<td></td>
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<tr>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>
Bioprosthesis Preparation

The bioprosthesis should be properly prepared as described earlier and irrigated frequently during implantation to prevent drying or dehydration of the tissue. The Tricentrix holder system should be properly deployed and the bioprosthesis should be adequately rinsed. If the holder system is handed to the surgeon in an undeployed fashion (the protective tenting system is not created) the surgeon or operative nurse can produce the deployment by gently holding the bioprosthesis sewing cuff, unlocking the post with a 1/4-clockwise turn to the handle (Figure 27), and pushing on the handle (Figure 28) until the tenting structure is produced and the post snaps into position. Do not implant the bioprosthesis if this tenting structure is not produced as it protects from looping a suture around the stent as well as aids insertion into the annulus (Figure 29). The bioprosthesis should be irrigated frequently (every 1-2 minutes) on both sides with saline to keep it moist during the implant procedure.

Figure 27. Unlock the post 1/4-clockwise turn.

Figure 28. Push on the handle until tenting structure is produced and post snaps into position.

Figure 29. Tenting structure protects against suture looping.
Implantation
Implantation

To produce the most natural flow the PERIMOUNT Magna mitral bioprosthesis should be oriented so that there is no obstruction of the LVOT by the post or strut of the bioprosthesis. In addition, the sewing cuff of the PERIMOUNT Magna mitral bioprosthesis is asymmetric and should be oriented so that the anterior saddle shape is positioned over the native anterior leaflet aiding in a natural distribution of chordal force if leaflet preservation techniques are used. This also positions the cuff regions of highest flexibility over the posterior annulus which is often calcified maximizing annular-cuff coaptation. To achieve proper orientation of the bioprosthesis, the anterior region of the sewing cuff (marked by the space between the two post or strut markers - one double and one single) should be positioned over the LVOT. This results in the double marking positioned near the anterior commissure of the native annulus, the single marking near the posterior commissure of the native valve, and the non-marked commissure of the bioprosthesis near the 6 o’clock position. Sutures are placed in the sewing cuff of the bioprosthesis making sure to properly orient the bioprosthesis (Figure 30).

Once all annular sutures are placed in the sewing cuff, the bioprosthesis is lowered using the handle and gentle traction on the sutures to maintain tension and avoid suture entrapment or tangling (Figure 31). The bioprosthesis is carefully inserted into the annulus by bending the handle sufficiently to enable the insertion of the posterior strut first and then the anterior portion.
of the bioprosthesis. This may help reduce the risk of damage to the ventricle or annulus. Once seated, approximation of the annulus and sewing cuff is checked.

![Image](image1.png)

**Figure 31. Bioprosthesis insertion with gentle suture traction to avoid tangling.**

The handle is released from the holder without unscrewing it by cutting the single green thread attaching the adapter to the post near the handle (Figure 32). This provides additional access and visibility for tying. Do not cut the three green threads on the legs that attach the holder to the bioprosthesis until all sutures have been tied. Sutures are tied being careful to check that seating does not shift and the sutures are seated normally. When cutting the suture tails verify that the knots or any remaining suture does not touch the leaflet tissue of the bioprosthesis as these may interfere with its function or cause abrasion to the leaflet.

![Image](image2.png)

**Figure 32. The single central green thread can be cut to quickly release the handle.**
Once all suture knots are tied, the holder is removed. In some cases one or two remaining sutures can be tied only by removing the holder first. In these cases all the sutures adjacent to each of the three frame struts must be tied down before cutting the holder attachment threads as the protective tenting is no longer in place after the holder is removed. The holder is released by cutting the three green threads on the legs of the holder. This is achieved by placing a scissors or cutting blade in the cutting channels (Figure 33). The holder is removed from the bioprosthesis by securing the bioprosthesis to the annulus and grasping the holder with sterile gloved hands or protected forceps and pulling it away from the bioprosthesis (Figure 34).

Figure 33. Three green threads are cut to remove the holder after all sutures are tied.

Figure 34. Holder is removed while securing the bioprosthesis to the annulus.
After the holder is removed, the bioprosthesis should be visually inspected for any defects that may have occurred during the implantation procedure. The bioprosthesis leaflets should appear symmetric and normal (Figure 35). Often a surgical mirror can be used to view the ventricular side of the bioprosthesis to check for proper suture placement. Unlike a repaired native mitral valve or porcine bioprosthesis, a saline bulb pressure test will not generate adequate pressures to fully close the PERIMOUNT Magna mitral bioprosthesis. However, a general assessment can be made by instituting antegrade cardioplegia while applying a saline bulb test. The aortic valve is frequently incompetent which greatly aids in increasing the left ventricular filling and end-diastolic pressure. The saline bulb test on the PERIMOUNT Magna mitral bioprosthesis results in centrally directed flow across the central free space of the valve. All PERIMOUNT valves are inspected while under physiological pressures to make certain coaptation and flow is within specification. The PERIMOUNT Magna mitral bioprosthesis was designed to fully close only under physiological pressures and should be assessed with TEE once volume loading is balanced and cardiac output reaches normal.

Figure 35. Visual inspection of bioprosthesis.
Post-implantation
Post-implantation

The mitral replacement procedure is often followed by a ligation of the left atrial appendage to prevent clot formation in patients with atrial fibrillation or enlarged atrium. Closure of the atrium is accomplished using a running polypropylene suture. Mitral replacement can be done with a concomitant coronary artery bypass graft. The bypass should be done first to reduce the risk of the bioprosthesis damaging tissue while lifting the heart and to aid in delivery of cardioplegia through the graft. On the other hand, tricuspid valve procedures are usually performed after replacing the mitral valve. In cases requiring both aortic and mitral valve replacement, generally the surgeon will excise the aortic valve and proceed to the mitral replacement. The aortic bioprosthesis is then sewn in after the mitral bioprosthesis is in place. Attempting to expose the mitral valve with an aortic bioprosthesis in place can be difficult and may require other techniques such as division of the atrial septum or the dome of the left atrium for adequate visualization.

Assessment

Trans-esophageal echocardiography (TEE) is particularly useful for imaging the mitral valve to detect proper bioprosthesis function and to aid in removal of intra-cardiac air prior to decannulation. Careful de-airing at the end of the operation is essential. Venting can be achieved through the left atrium, the aorta, and sometimes the left ventricle apex. Once de-airing maneuvers are completed, the cross-clamp can be released and the patient is completely re-warmed. The venous return can then be occluded partially and the heart is then gradually loaded as any necessary pharmacological agents are given. Pulmonary artery pressures should be carefully monitored. Temporary epicardial pacing wires may be placed at the right atrium and the right ventricle to suppress atrial and ventricular tachyarrhythmias.

Once volume loading is balanced and cardiac output approaches normal, the PERIMOUNT Magna mitral bioprosthesis can be imaged by TEE for assessment of bioprosthesis function. Similar to most prosthetic valves, PERIMOUNT bioprostheses exhibit a unique pattern of signature flow which is normal (Figure 36). Normally functioning PERIMOUNT bioprostheses demonstrate on TEE trace or mild central regurgitation from the free space at the center of the bioprosthesis. As the left ventricle returns to physiologic pressures following bypass, the appearance of any central jet should diminish
until only trivial or mild signature flow remains. Normal pressures may take more than 45 minutes to be reached. Similarly, prior to heparin reversal, the bioprosthesis may show some temporary minor jets through the sewing ring cloth prior to administration of protamine. This type of flow will resolve as heparin is reversed.

If there is detection of 2+ or greater central regurgitation or the presence of a moderate eccentric jet then this indicates a problem. Excessive regurgitation (especially severe regurgitation), eccentric regurgitant jets, or a restricted appearance of the leaflets on echocardiographic assessment may indicate an entrapped leaflet. In this case the bypass should be reinstituted and the atrial incision should be reopened for further assessment.

**Antithrombogenic Therapy**

Anticoagulation is prescribed for all patients undergoing mitral valve replacement. The therapeutic international normalized ratio (INR) for patients after mitral valve replacement ranges from 2.5-3.5 and warfarin therapy is usually started on the second postoperative day. Various methods of heparin or dextran bridging therapy can be used until the warfarin has reached therapeutic level. The INR levels can be in the low range for patients in sinus rhythm with PERIMOUNT Magna mitral bioprosthesis. Patients can be evaluated in 6-12 weeks for any rhythm disturbances and if they are predominantly in sinus rhythm, warfarin is stopped. All mitral replacement patients are recommended aspirin therapy daily indefinitely.
NOTES:
NOTES:
No clinical data are available which evaluate the long-term impact of the Edwards Lifesciences tissue treatment in patients. The surgical technique presented herein is the technique used by Allen Morris, M.D. Edwards Lifesciences does not endorse any particular surgical technique.

Allen Morris, M.D. is a paid consultant to Edwards Lifesciences.

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