

# Carpentier-Edwards PERIMOUNT Plus Mitral Pericardial Bioprosthesis with Tricentrix Holder System: Sizing and Implantation Technique

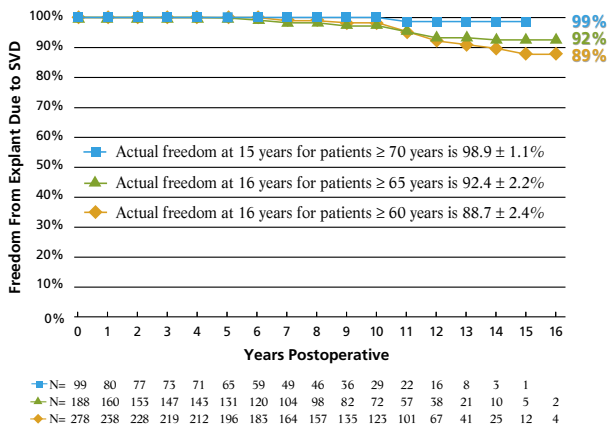
## Carpentier-Edwards PERIMOUNT Plus Mitral Pericardial Bioprosthesis

The Carpentier-Edwards PERIMOUNT mitral pericardial bioprosthesis was introduced into clinical use in Europe and Canada in 1984 and approved for US distribution in 2000. Its unique design maximizes durability and enhances hemodynamic performance (Figure 1).



**Figure 1**  
Carpentier-Edwards PERIMOUNT Plus Pericardial Mitral Bioprosthesis

The valve profile, shape and leaflet mounting technique were engineered to enhance durability by increasing tolerance for the high pressure under which a mitral bioprosthesis functions. Clinical studies of the mitral PERIMOUNT valve demonstrate excellent freedom from structural valve deterioration<sup>1,2</sup> (Figure 2).



**Figure 2**  
Actual Freedom From Explant Due to SVD

## Implantation Considerations

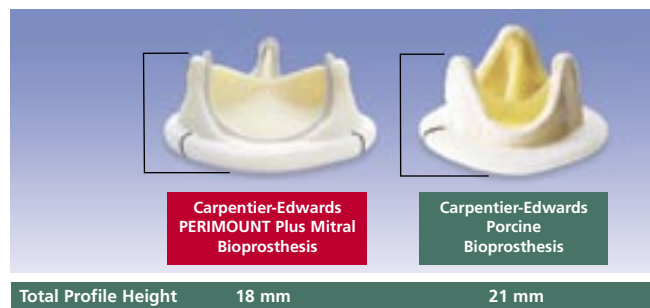
The Carpentier-Edwards PERIMOUNT Plus mitral pericardial bioprosthesis is implanted using standard surgical techniques.

The standard implantation technique includes:

1. Proper sizing
2. Proper seating of the prosthesis
3. Tying sutures with the holder in place to avoid suture looping or chordal entrapment
4. Examination of the valve leaflets for distortion or leak during tying

The Carpentier-Edwards PERIMOUNT Plus mitral pericardial bioprosthesis has an innovative low profile design with short struts as compared to porcine valves. This feature minimizes the risk of left ventricular outflow tract obstruction by the prosthesis and the risk of ventricular damage in patients with a small ventricular cavity (Figure 3).

Nonetheless, as with any stented mitral bioprosthesis, special care must be taken during implantation to avoid looping a suture around one of the strut posts or inserting a post behind a strand of chordal tissue when chordal preservation techniques are used.



**Figure 3**  
Comparison of 27 mm Valves

## 1. Sizing

It is essential to use the 1169P sizers designed for the mitral PERIMOUNT Plus valve. Sizer dimensions correlate with those of the valve (Figure 4).



Figure 4  
Sizer Model 1169P

The sizer should fit comfortably in the annulus. The lip of the sizer mimics the valve sewing ring and helps the surgeon to anticipate the outcome of specific implantation techniques.

Chordal preservation techniques may decrease the size of valve that can be implanted. With chordal sparing, the preserved leaflets are reefed within the valve-sutures and compressed between the sewing ring and the native annulus, thereby decreasing the size of the annulus.<sup>3</sup>

When using this technique, it is recommended that the surgeon sizes the valve after sutures have been placed to ensure that sizing is more accurate and to avoid placing too large a valve.

### Upsizing

Upsizing may cause valve damage or localized mechanical stresses, which may in turn injure the heart or result in tissue failure, stent distortion and valve regurgitation. The excellent hemodynamic performance of the mitral PERIMOUNT Plus valve across all sizes makes upsizing unnecessary (Figure 5).

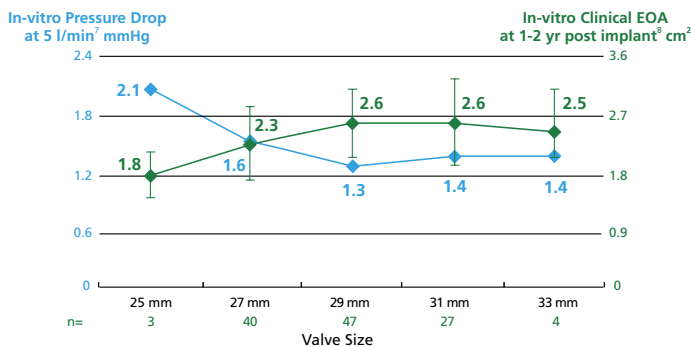


Figure 5  
Hemodynamic Performance

## 2. Valve Holder

The Tricentrix holder system provides ease of use and increased visibility. Its innovative tenting system protects the struts from entrapping a loose suture or chordae. The three stent posts retract toward the center of the valve when the Tricentrix holder system is fully deployed.

To deploy the Tricentrix holder system, the scrub nurse should follow these steps:

- Insert the handle 1111 (reusable) or 1126 (disposable) and turn clockwise until snug fit;
- Grasp the plastic sleeve and rotate the handle clockwise until the holder reaches the unlock position, remove the cap, then push on the handle until the post snaps into its fully deployed position (Figure 6).



Rotate



Push

Figure 6

- Remove the sleeve and clip. Rinse the valve two times, one minute each, in separate saline bowls filled with at least 500 ml.
- 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 (Figure 7).



Rotate • Push • Snap



Push • Snap



Implant

Figure 7  
Check for Proper Deployment

Once the handle has been attached, it should not be removed from the holder until the valve is seated in the annulus. Prior to tying the sutures, the handle of the valve holder may be removed. This is easily achieved without unscrewing it: the handle and adapter can be removed as an assembly. Maintain the valve placement in the annulus by gently placing forceps or gloved hands onto the holder. Cut the adapter attachment thread by the handle (Figure 8) and remove the adapter and handle assembly as one unit.

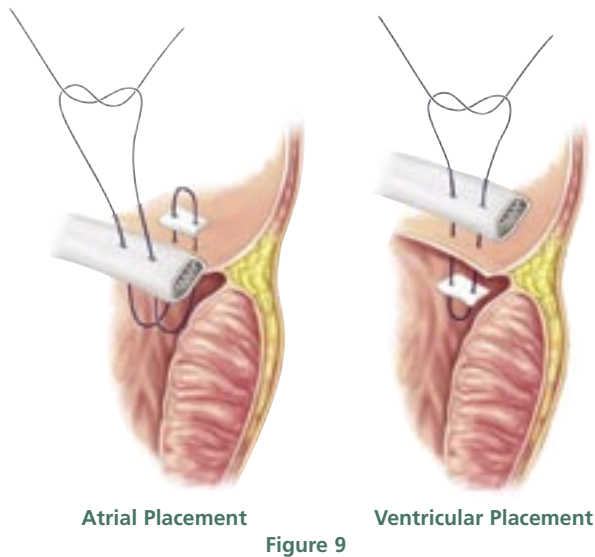


Figure 8

However, it is essential to leave the valve holder attached to the valve while tying the sutures.

### 3. Suture Technique

Like other mitral bioprostheses, the mitral PERIMOUNT Plus valve is usually implanted using pledgeted mattress sutures. The pledgets may be placed either on the atrial or ventricular aspect of the annulus. Ventricular placement is sometimes preferred in the case of a calcified annulus (Figure 9).



With chordal-preserving techniques, pledget-reinforced horizontal mattress valve sutures are passed from the left atrium, through the mitral annulus, around the free edge of the mitral leaflet, and up through the prosthesis sewing ring. The valve is seated and the sutures tied, reefing the native leaflets and compressing them between the sewing ring and native annulus.<sup>4</sup> Maintain firm tension on the sutures as the valve is lowered into the annulus to prevent formation of suture loops that might entrap a leaflet.

### 4. Valve Orientation

Two suture markers aid in the orientation of the valve. The mitral PERIMOUNT Plus valve is symmetrical and offers three identical leaflets without muscle shelves. The valve should be positioned to avoid obstruction of the left ventricular outflow tract by the struts.

### 5. Removal of the Valve Holder

To avoid suture looping, it is essential to leave the deployed holder in place until **all knots are tied**.

#### Avoid suture looping

If leaving the holder in place obstructs the surgeon's view, **all the sutures adjacent to each of the three stent posts MUST be tied down before cutting the three holder attachment threads to remove the holder.**

If the deployed holder attachment threads are cut before these adjacent sutures are tied down, the holder can no longer prevent suture looping around the stent posts.

Without these attachment sutures, the valve could also unseat or partially separate from the annulus during the removal of the holder, loosening the sutures which may in turn result in a suture loop.

Special attention must be given to avoid tying the sutures on top of the corners of the holder legs.

The holder is easily removed by cutting each of the three green exposed threads using a scalpel or scissor placed in the cutting channel, then removing the holder system as a unit, along with attaching sutures using sterile gloved hands or protected forceps (Figure 10).

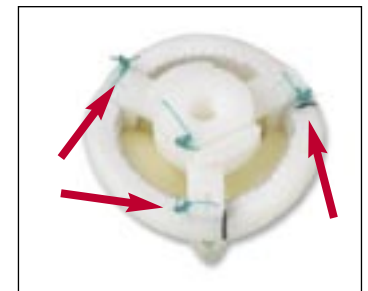


Figure 10

### 6. Assessment of Sutures

Before tying each suture, examine the valve leaflets while holding the two strands of the suture under tension. Distortion or movement of the valve leaflets during this maneuver suggests that the suture is looped around a strut. If leaflet movement or distortion is observed, the strut closest to the suture is examined and the suture slipped off the strut. A surgical mirror may be placed through the valve leaflets in order to ensure proper suture placement (Figure 11).

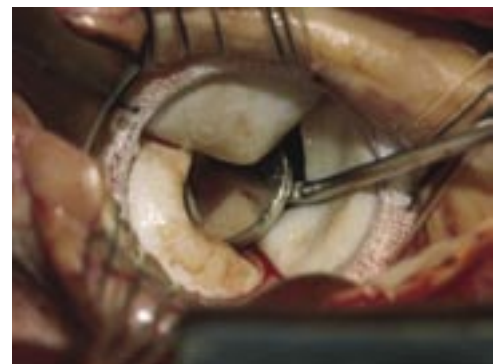


Figure 11

## Special Considerations

After all sutures are tied, the ventricle is filled with saline under pressure to assess valve function. Antegrade cardioplegia may also be administered to pressurize the left ventricle. The leaflets should appear symmetric, and there is usually a small central jet of regurgitation. Leaflet distortion or a major jet arising elsewhere suggests a technical problem. In such an instance, the ventricular aspect of the valve should be examined with a surgical mirror in order to ensure correct suture placement and no suture or chordal entrapment.

## Echocardiographic Assessment

As with any heart valve operation, intraoperative post-bypass transesophageal echo verification of valve function prior to heparin reversal and decannulation is essential.<sup>5</sup> Normally functioning valves demonstrate no or mild central regurgitation arising from the free space at the center of the valve. Occasionally one or more trivial jets arise from the coaptation edge of the leaflets and originate at the stent posts. All of these flow patterns are physiologically insignificant and comprise this valve's signature flow pattern (Figure 12).



**Figure 12**  
**Signature Flow Pattern: Trivial MR**

Additional flow patterns observed include minor jets originating from the sewing ring cloth that may be observed prior to administration of protamine. Unlike the signature flow pattern, these jets typically resolve shortly after reversal of heparin. Similarly, as the patient returns to physiologic

pressures following cardiopulmonary bypass, the appearance of the central jet diminishes until only trivial or mild signature flow remains.<sup>6</sup>

Abnormal flow patterns include moderate (2+) or greater central or eccentric regurgitation. Excessive regurgitation, especially severe regurgitation or a restricted appearance of the leaflets on echocardiographic assessment may indicate an entrapped leaflet and requires reinstatement of cardiopulmonary bypass and re-opening of the atrial incision for further assessment.

**The surgical technique presented in this paper is the technique developed by A. Marc Gillinov, M.D. Edwards Lifesciences does not endorse any particular surgical technique. See the instructions for use that accompany the product for full prescribing information.**

Surgical photos courtesy of Delos Cosgrove, M.D., The Cleveland Clinic Foundation.

### References

- 1 Marchand MA, et al. Fifteen-Year Experience With the Mitral Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis. *Ann Thorac Surg* 2001; 71:5236-9.
- 2 Data on file at Edwards Lifesciences - 16 YEAR RESULTS Carpentier-Edwards PERIMOUNT Mitral Pericardial Bioprosthesis, Model 6900 CLINICAL COMMUNIQUE
- 3 Aagaard J, et al. Mitral valve replacement with total preservation of native valve and subvalvular apparatus. *J Heart Valve Dis.* 1997 May;6(3):274-8; discussion 279-80
- 4 Yu Y, et al. Mitral valve replacement with complete mitral leaflet retention: operative techniques. *J Heart Valve Dis.* 1999 Jan;8(1):44-6
- 5 Shanewise JS et al: ASE/SCA guidelines for performing a comprehensive intraoperative multiplane transesophageal echocardiography examination: Recommendations of the American Society of Echocardiography Council for Intraoperative Echocardiography and the Society of Cardiovascular Anaesthesiologists Task Force for Certification in Perioperative Transesophageal Echocardiography. *J Am Soc Echocardiogr* 1999; 12:884-900
- 6 Morehead AJ et al. Intraoperative echocardiographic detection of regurgitant jets after valve replacement. *Ann Thorac Surg* 2000;69:135-139.
- 7 Data on file at Edwards Lifesciences - RD346
- 8 Carpentier-Edwards PERIMOUNT Plus Mitral Pericardial Bioprosthesis product insert - Directions for use.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information.

Edwards Lifesciences devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Edwards Lifesciences, Edwards, the stylized E Logo and Tricentric are trademarks of Edwards Lifesciences Corporation. Carpentier-Edwards, PERIMOUNT and PERIMOUNT Plus are trademarks of Edwards Lifesciences Corporation and are registered in the U.S. Patent and Trademark Office.

© 2004 Edwards Lifesciences LLC  
All rights reserved. AR00639



# Edwards Lifesciences