Carpentier-Edwards PERIMOUNT Mitral Valves
Models 6900P and 6900PTFX
Sizing and Implantation Technique

Device description
The Carpentier-Edwards PERIMOUNT Plus mitral pericardial bioprosthesis, model 6900P, and the Carpentier-Edwards PERIMOUNT Theon mitral pericardial bioprosthesis, model 6900PTFX, are comprised of bovine pericardium leaflets mounted on a flexible metal alloy frame. Both valves are built upon the proven performance of model 6900 in clinical use since 1984.2

The valve profile, shape and mounting techniques have been specifically engineered to enhance durability by increasing tolerance for the high pressure under which a mitral bioprosthesis functions.

Carpentier-Edwards PERIMOUNT mitral valves are compatible with the following accessories (Figure 1):

- Handle model 1117
- Sizers model 1169HP
- Tray model TRAY1169HP

Implantation
The Carpentier-Edwards PERIMOUNT valve is implanted using standard surgical techniques. Key steps to a successful implant include:

1. Proper sizing with the appropriate valve sizers.
2. Proper preparation and seating of the bioprosthesis using the handle and properly deployed holder.
3. Proper use of the holder; tying sutures with the holder in place to avoid looping around the stent.
4. Proper assessment of function, both by direct vision before closure, then with postoperative TEE.

1. Sizing
Use only Edwards sizers 1169HP to size for Carpentier-Edwards PERIMOUNT mitral valves, models 6900P and 6900PTFX, as their key dimensions correlate with those of the valves (Figure 2):

- the barrel's external diameter matches the valve's external diameter (OD),
- the lip of the sizer mimics the sewing band.

Figure 1
- Figure 2
1. Do not oversize!
Oversizing 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 PERIMOUNT mitral valve across all sizes makes oversizing unnecessary (Figure 3).

Sizers 1169HP are labeled with both the valve size and the mean effective orifice area (EOA) in cm² (Figure 4). These in vivo EOA values were obtained through three multicentric prospective studies conducted between 1984 and 1997 at the 1- to 2-year post-implant interval. Having access to both the labeled size and the EOA at the time of surgery provides clinically relevant information on the expected hemodynamic performance. This may help surgeons determine the right size for a particular patient, and prevent oversizing.

1.2 Sizing according to the suture technique
Like other mitral bioprostheses, PERIMOUNT mitral valves are usually implanted using pledgeted mattress sutures. The pledgets may be placed either on the atrial or ventricular aspect of the annulus (Figure 5). The suggested suture technique is ventricular placement of the pledgets or non-evertting sutures as this allows the valve and annulus to seat in the most natural position and is often preferred in the case of a calcified annulus.

When sizing for non-evertting suturing techniques, the sizer barrel should comfortably fit when introduced into the annulus. The sizer lip should be seated on top of the annulus as the sewing band will be later. It is important to account for a possible decrease in the size of the valve that can be implanted when chordal preservation techniques are used.14

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**Figure 3**
Hemodynamic Performance

**Figure 4**

**Figure 5**
2. Preparation and seating of the prosthesis

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

2.1 Deploy the Tricentrix holder system

![Figure 7]

The Tricentrix holder system (Figure 7) facilitates implantation while maximizing visibility. Its innovative tenting system protects the stent from entrapping a loose suture. 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, these steps must be followed:

- 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 valve is seated in the annulus.

- Grasp the plastic sleeve and rotate the handle clockwise an additional 1/4-turn until the holder reaches the unlock position; then push on the handle until the post snaps into its fully deployed position (Figure 8).

![Figure 8]

- Remove the sleeve and clip. The sleeve is removed by pulling away from the rest of the assembly. The clip then is removed by sliding away from the holder. Rinse the valve two times, one minute each, in separate saline bowls filled with at least 500 ml saline.

- 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 9).

![Figure 9]

Should the surgeon suspect that the holder is not fully deployed when handed the valve, he or she can complete the deployment by gently holding the valve sewing band, unlocking the post, and pushing on the handle until the tenting structure is produced and the post snaps into position.
2.2 Valve orientation
The PERIMOUNT mitral 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 (LVOT) by the stent posts. Two black suture markers aid in the orientation of the valve and indicate where the stent posts are positioned.

The PERIMOUNT mitral valve has a low profile design with short stent posts. This feature also minimizes the risk of LVOT obstruction and the risk of ventricular damage in patients with a small ventricular cavity.

2.3 Valve seating
It is important to 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 (Figure 10). The 1117 handle is longer and has a flexible shaft to help reach difficult exposures and to facilitate valve seating.

3. Tying sutures with the holder in place

3.1. Handle removal
Once the valve is seated, the handle of the valve holder system may be removed prior to tying the sutures. This is easily achieved without unscrewing it: the handle and adapter are removed as an assembly. Maintain the valve placement in the annulus by gently placing forceps or gloved hands onto the holder.

Cut the single green adapter attachment thread by the handle and remove the adapter and handle assembly as one unit (Figure 11). Do not unscrew the handle as this may unseat or rotate the valve, creating the potential for a loose suture.

3.2. Avoid suture looping
To avoid suture looping, it is essential to leave the deployed Tricentrix holder attached to the valve until all knots are tied.

The Tricentrix holder system has short legs and rounded edges for ease of suturing and a very low profile for increased visibility.

However, if leaving the holder in place obstructs the surgeon’s view or makes tying knots difficult, at least all the sutures to each side of the three stent posts MUST be tied down before cutting the three holder attachment threads to remove the holder.

Do not cut the deployed holder attachment threads before these adjacent sutures are tied down. If the attachment threads are cut before tying the sutures, the holder tenting structure will be eliminated and can no longer prevent suture looping around the stent posts. In addition, 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.
3.3. Tricentrix holder removal

Once all knots are tied, the holder is easily removed by cutting each of the three green exposed threads using a scalpel or scissors 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 12).

![Figure 12](image)

4. Assessment of the valve function

4.1. Direct vision assessment

Once the holder is removed it is important to visually assess the function of the valve. The leaflets should appear symmetric; any leaflet distortion suggests a technical problem. It is recommended to visually inspect each of the leaflets to ensure the valve is free of suture loops or anatomical obstructions that may interfere with the function of the valve.

The PERIMOUNT valve design incorporates a small central free space at rest. This space is intended to relieve stress on the tissue and to contribute thereby to the long-term performance of the valve. It closes under even low physiological pressure. However, the “water test”, which is filling the left ventricle with saline using a syringe, widely used in mitral valve repair, is not recommended to test the PERIMOUNT mitral valve.

4.2. 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. 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. 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. 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 reinstitution of cardiopulmonary bypass and re-opening of the atrial incision for further assessment (Figure 13).

![Figure 13](image)
References
2. Data on File at Edwards Lifesciences - 10 YEAR RESULTS Carpentier-Edwards PERIMOUNT Mitral
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