Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis Model 6900 Mitral
Instructions for Use

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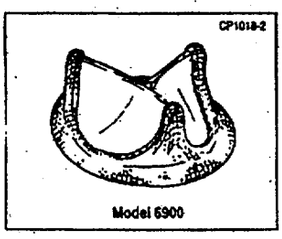


Instructions for Use

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

1. DEVICE DESCRIPTION

The Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis Model 6900 Mitral is a trileaflet stent-supported bioprosthetic valve comprised of bovine pericardium mounted on a flexible frame. The bioprosthesis is treated according to the Edwards XenoLogiX process, which uses ethanol and polysorbate-80 (a surfactant), and is packaged and terminally sterilized in glutaraldehyde. Glutaraldehyde is shown to both reduce the antigenicity of tissue xenograft valves and increase tissue stability; however, glutaraldehyde has not been shown to affect or reduce the calcification rate of the valve.

The Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis Model 6900 Mitral is designed for the mitral position and is available in the sewing ring diameters and sizes shown in Figure 1.

The flexible frame or wireform of the valve is composed of Elgiloy and is covered with a woven polyester cloth. It is designed to be compliant at the orifice and commissures to reduce the closing loading shocks at the commissure tips and free margin of the leaflets.

An Elgiloy band attached to a polyester film band surrounds the base of the wireform frame, providing structural support for the orifice and identification radiologically. A suture ring covered with polytetrafluoroethylene (PTFE) cloth is attached to the wireform frame. The suture ring contains inserts of silicone rubber and non-woven polyester.

Two contrasting marking sutures are located on the sewing ring. These sutures are intended to aid in the proper orientation for implanting the prosthesis.

2. INDICATIONS

The Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis Model 6900 Mitral is indicated for patients who require replacement of their native or prosthetic mitral valve.

3. CONTRAINDICATIONS

None known.

4. WARNINGS

FOR SINGLE USE ONLY.

DO NOT RESTERILIZE THE VALVE BY ANY METHOD. Exposure of the bioprosthesis or container to irradiation, steam, ethylene oxide, or other chemical sterilants will render the bioprosthesis unfit for use.

DO NOT FREEZE OR EXPOSE THE VALVE TO EXTREME HEAT. Each bioprosthesis in its jar is shipped in a molded foam enclosure containing two temperature indicators, which are intended for monitoring the temperature to which the device is exposed during transit. If either indicator has been activated, indicating that the valve has been exposed to freezing temperatures or has had prolonged exposure to heat, do not use the valve. Please refer to the **Storage** section for further instructions.

WARNING: Studies have NOT been performed to evaluate the safety or compatibility of this valve during magnetic resonance imaging (MRI) scans. As such, the potential hazards of MRI testing on patients receiving this bioprosthesis are unknown.

WARNING: Accelerated deterioration due to calcific degeneration of the bioprosthesis may occur in:

- children, adolescents, or young adults;
- patients with abnormal calcium metabolism (e.g., chronic renal failure or hyperparathyroidism).

5. PRECAUTIONS

- The outside of the jar is not sterile and must not be placed in the sterile field.
- Do not use the bioprosthesis if the tamper evident seal is broken.
- Do not use the bioprosthesis if the container is leaking, damaged, or the glutaraldehyde solution does not completely cover the bioprosthesis.
- Adequate rinsing with physiological saline must be performed before implantation to reduce the glutaraldehyde concentration.
- Do not expose the valve to any solutions, chemicals, antibiotics, or other drugs, except for the storage solution or sterile physiological saline solution, as irreparable damage to the leaflet tissue may result that is not apparent under visual inspection.

- Do not allow the valve tissue to dry. It must be kept moist at all times. Maintain tissue moisture with sterile physiological saline irrigation on both sides of the leaflet tissue.
- Do not pass catheters, transvenous pacing leads, or any surgical instrument across the valve since they may cause tissue damage.
- Care must be taken when performing open and closed chest cardiac massage in patients with an open strut mitral prosthesis due to increased risk of ventricular perforation.

CAUTION: Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure or breathing of the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water. In the event of contact with the eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, please refer to the Material Safety Data Sheet MSDI0424 available from Edwards Lifesciences.

6. ADVERSE EVENTS

6.1. Observed Adverse Events

Three (3) multi-center, non-randomized, prospective, non-US clinical studies were conducted of patients implanted with the Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis Model 6900 Mitral. Three hundred-one (301) patients had isolated mitral valve replacement (MVR) and 62 patients had double valve replacement (DVR), where the aortic valve was replaced with a Carpentier-Edwards Pericardial Bioprosthesis aortic model. One study was conducted between 1984 and 1986, the second study was conducted between 1989 and 1994, and the third study was conducted between 1996 and 1997. Patients were evaluated preoperatively, intraoperatively/at discharge, at 1 year, and annually thereafter. Adverse events were captured throughout the postoperative period.

Table 1 presents the observed rates for early events (≤ 30 days), the linearized rates for late events (> 30 days postoperatively), and the actuarial adverse event rates at 1, 5, and 8 years postoperatively.

The adverse event rates were based on 363 patients at 9 centers. The cumulative follow-up was 1100 patient-years with a mean follow-up of 3.0 years (SD = 2.4 years, range = 0 to 8.2 years).

Table 1: Observed Adverse Event Rates for MVR and DVR
All patients analyzed: N = 363 Cumulative follow-up: 1100 patient-years

Complication	Early Events		Late Events[1]		Freedom from Event (%) [95% CI][2]		
	n[3]	%	n	%/pt-yr	1 year (n = 363)	5 years (n = 141)	8 years (n = 18)
Mortality (all)	34	9.4	50	4.7	85.5 [81.8, 89.2]	75.4 [70.3, 80.6]	65.4 [57.6, 73.2]
Mortality (valve-related)	0	0	16	1.5	97.7 [96.0, 99.4]	95.3 [92.8, 97.8]	91.9 [87.5, 96.4]
Explants	0	0	8	0.7	98.7 [98.0, 99.3]	96.7 [95.3, 98.0]	95.6 [93.9, 97.3]
Reoperations	2	0.6	12	1.1	97.1 [96.2, 98.1]	95.1 [93.6, 96.6]	93.0 [90.9, 95.1]
Anticoagulant-related hemorrhage	2	0.6	9	0.8	97.1 [95.2, 99.0]	97.1 [95.2, 99.0]	94.1 [88.2, 100]
Endocarditis	1	0.3	3	0.3	99.0 [97.9, 100]	98.7 [97.4, 98.9]	98.7 [97.4, 98.9]
Hemolysis	0	0.0	1	0.1	99.7 [99.0, 100]	99.7 [99.0, 100]	99.7 [99.0, 100]
Nonstructural dysfunction	0	0.0	3	0.3	100 [100, 100]	99.3 [98.0, 100]	98.3 [95.9, 100]
Perivalvular leak (all)	1	0.3	5	0.5	98.4 [97.0, 99.8]	98.4 [97.0, 99.8]	97.3 [94.9, 99.8]
Structural valve deterioration	0	0.0	5	0.5	100.0 [100, 100]	97.6 [95.2, 100]	92.8 [85.3, 100]
Thromboembolism	5	1.4	8	0.7	97.5 [95.8, 99.2]	96.1 [93.8, 98.5]	96.1 [93.8, 98.5]
Thrombosis	0	0.0	0	0.0	100.0 [100, 100]	100.0 [100, 100]	100.0 [100, 100]

Notes:
1. Late event rates were calculated as linearized rates (%/pt-yr) based on 1072.5 late patient-years (> 30 days postoperatively).
2. Freedom from event rates were calculated using the Kaplan-Meier method. Greenwood's formula was used for calculation of the standard errors of these estimates.
3. n = number of patients

6.2. Potential Adverse Events

Adverse events potentially associated with the use of bioprosthetic heart valves includes:

- death
- endocarditis
- hemolysis
- hemorrhage (anticoagulant/antiplatelet-related or other)
- nonstructural dysfunction (entrapment by pannus, tissue, or suture; inappropriate sizing or positioning; or other)
- paravalvular leak
- structural deterioration (calcification, wear, leaflet tear, stent creep, or other)
- thromboembolism
- valve thrombosis

Other adverse events associated with the use of Carpentier-Edwards PERIMOUNT Pericardial Bioprostheses Model 6900 Mitral compiled from the literature and from reports received through Edwards Lifesciences complaint handling system include: stenosis, regurgitation through an incompetent valve, ventricular perforation by stent posts, malfunctions of the valve due to distortion at implant, or fracture of the Elgiloy wireform.

7. CLINICAL STUDIES

The safety endpoints captured in the prospective studies were complications; blood analyses were used to confirm the absence or presence of certain complications. The safety results are provided above in Table 1. Effectiveness endpoints were New York Heart Association (NYHA) functional classification and echocardiographic assessments. Preoperative and operative patient demographics are presented below, followed by the effectiveness results.

Table 2: Preoperative Patient Demographics

Variable	Category	Study Characteristics (N=363; 1100 total pt-yrs.)	
		n	% (n/N)[1]
Age at implant	Mean ± SD	363	66.1 ± 10.7
Gender	Female/Male	212/151	58.4%/41.6%
Diagnosis	None	30	8.3%
	Stenosis	91	25.1%
	Regurgitation	184	50.7%
	Mixed Disease	58	16.0%

Note:

1. n = number of patients in each category; N = total number of study patients.

Table 3: Operative Patient Demographics

Variable	Category	Study Characteristics (N=363; 1100 total pt-yrs.)	
		n	% (n/N)[1]
Etiology[2]	Rheumatic Heart Disease	135	37.2%
	Calcification	82	22.6%
	Degeneration	50	13.8%
	Endocarditis	39	10.7%
	Failed Bioprosthesis	15	4.1%
	Ischemic Heart Disease	14	3.9%
	Congenital Abnormalities	8	2.2%
	Other	44	12.1%
Concomitant Procedures[2]	None	200	55.1%
	CABG[3]	78	21.5%
	Tricuspid Repair	61	16.8%
	Intra-Aortic Balloon Pump	17	4.7%
	Pacemaker[4]	6	1.7%
	Aortic Repair/Replacement	5	1.4%
	Aneurysm Repair	4	1.1%
	Other	31	8.5%
Pre-existing Conditions[2]	None	122	33.6%
	CAD[5]/CABG	72	19.8%
	Hypertension	61	16.8%
	Atrial Fibrillation	53	14.6%
	Previous MI[6]	45	12.4%
	Cerebrovascular Disease	36	9.9%
	Other	234	64.5%
Valve Size (mm)	25	22	6.1%
	27	110	30.3%
	29	137	37.7%
	31	81	22.3%
	33	13	3.6%

Notes:
1. n = number of patients in each category; N = total number of study patients
2. May be more than one per patient
3. CABG = Coronary Artery Bypass Graft Surgery
4. Permanent or temporary
5. CAD = Coronary Artery Disease
6. MI = Myocardial Infarction

Table 4: Effectiveness Outcomes, Functional NYHA

NYHA Functional Class	Preoperative Assessment		Postoperative Assessments			
			1 to 2 Year		5 Year	
	n/N[1]	%	n/N	%	n/N	%
I	11/363	3.0	120/268	44.8	40/129	31.0
II	73/363	20.1	90/268	33.6	25/129	19.4
III	192/363	52.9	15/268	5.6	1/129	0.8
IV	84/363	23.1	0/268	0.0	0/129	0.0
Not Available	3/363	0.8	43/268	16.0	63/129	48.8

Note:
1. n = number of patients in each category; N = total number of study patients

Table 5: Effectiveness Outcomes, Hemodynamic Results[1]

Hemodynamic Parameter	Results By Valve Size				
	25mm	27mm	29mm	31mm	33mm
Mean Gradien[4]	n = 3	n = 23	n = 36	N = 23	n = 3
• mean ± sd	5.7 ± 1.2	4.2 ± 1.7	4.2 ± 1.7	3.6 ± 1.0	7.5 ± 5.8
• min, max	5, 7	2, 9	1, 8	2, 5	3, 14
EOA[5]	n = 1	n = 17	n = 22	n = 25	n = 5
• mean ± sd	1.5	2.9 ± 0.9	3.1 ± 0.9	2.5 ± 0.7	3.0 ± 1.2
• min, max	1.5, 1.5	1.3, 4.1	1.4, 4.2	1.5, 3.8	1.6, 4.9
Regurgitation[6]	n = 3	n = 28	n = 51	n = 40	n = 8
0	3/3 (100%)	22/28 (79%)	36/51 (71%)	30/40 (75%)	4/8 (50%)
1+	0/3 (0%)	5/28 (18%)	13/51 (25%)	7/40 (18%)	4/8 (50%)
2+	0/3 (0%)	0/28 (0%)	1/51 (2%)	3/40 (7%)	0/8 (0%)
3+	0/3 (0%)	0/28 (0%)	1/51 (2%)	0/40 (0%)	0/8 (0%)
4+	0/3 (0%)	0/28 (0%)	0/51 (0%)	0/40 (0%)	0/8 (0%)
Not Available	0/3 (0%)	1/28 (3%)	0/51 (0%)	0/40 (0%)	0/8 (0%)
Mean Gradient[4]	n = 5	n = 19	n = 15	n = 5	n = 2
• mean ± sd	6.4 ± 1.7	5.3 ± 5	3.4 ± 1.2	4 ± 1.9	4 ± 0
• min, max	5, 9	2, 25	2, 6	2, 7	4, 4
EOA[5]	n = 5	n = 18	n = 13	n = 5	n = 2
• mean ± sd	2.9 ± 0.8	2.6 ± 0.7	2.8 ± 0.6	2.9 ± 0.3	2.6 ± 1
• min, max	1.8, 3.6	1.5, 5	2, 3.8	2.4, 3.3	2, 3.3
Regurgitation[6]	n = 5	n = 21	n = 15	n = 6	n = 2
0	3/5 (60%)	17/21 (81%)	6/15 (40%)	4/6 (67%)	1/2 (50%)
1+	0/5 (0%)	4/21 (19%)	8/15 (53%)	2/6 (33%)	0/2 (0%)
2+	1/5 (20%)	0/21 (0%)	1/15 (7%)	0/6 (0%)	1/2 (50%)
3+	0/5 (0%)	0/21 (0%)	0/15 (0%)	0/6 (0%)	0/2 (0%)
4+	1/5 (20%)	0/21 (0%)	0/15 (0%)	0/6 (0%)	0/2 (0%)
Not available	0/5 (0%)	0/21 (0%)	0/15 (0%)	0/6 (0%)	0/2 (0%)
Mean Gradient[4]	n = 3	n = 40	n = 47	n = 27	n = 4
• mean ± sd	5.2 ± 0.7	4.1 ± 1.6	3.5 ± 1.8	3.1 ± 1.4	2.1 ± 0.5
• min, max	4.7, 6	1, 7	1, 10	1,7	1.5, 2.7
EOA[5]	n = 2	n = 35	n = 46	n = 29	n = 5
• mean ± sd	1.8 ± 0.4	2.3 ± 0.6	2.6 ± 0.5	2.6 ± 0.7	2.5 ± 0.5
• min, max	1.5, 2.0	1.2, 3.5	1.1, 3.7	1.1, 3.7	2.1, 3.2
Regurgitation[6]	n = 4	n = 42	n = 51	n = 29	n = 5
0	2/4 (50%)	31/42 (74%)	36/51 (71%)	17/29 (59%)	3/5 (60%)
1+	1/4 (25%)	9/42 (21%)	11/51 (21%)	8/29 (27%)	1/5 (20%)
2+	1/4 (25%)	2/42 (5%)	4/51 (8%)	2/29 (7%)	1/5 (20%)
3+	0/4 (0%)	0/42 (0%)	0/51 (0%)	2/29 (7%)	0/5 (0%)
4+	0/4 (0%)	0/42 (0%)	0/51 (0%)	0/29 (0%)	0/5 (0%)
Not Available	0/4 (0%)	0/42 (0%)	0/51 (0%)	0/29 (0%)	0/5 (0%)
Mean Gradient[4]	n = 0	n = 6	n = 5	n = 0	n = 0
• mean ± sd	N/A[7]	8.8 ± 8.1	5.1 ± 2.3	N/A	N/A
• min, max	N/A	4, 25	3, 8	N/A	N/A
EOA[5]	n = 0	n = 2	n = 4	n = 0	n = 0
• mean ± sd	N/A	2.0 ± 1.5	2.9 ± 0.6	N/A	N/A
• min, max	N/A	1.0, 3.1	2.1, 3.5	N/A	N/A
Regurgitation[6]	n = 0	n = 6	n = 5	n = 0	n = 0
0	0/0 (0%)	4/6 (66%)	2/5 (40%)	0/0 (0%)	0/0 (0%)
1+	0/0 (0%)	1/6 (17%)	3/5 (60%)	0/0 (0%)	0/0 (0%)
2+	0/0 (0%)	1/6 (17%)	0/5 (0%)	0/0 (0%)	0/0 (0%)
3+	0/0 (0%)	0/6 (0%)	0/5 (0%)	0/0 (0%)	0/0 (0%)
4+	0/0 (0%)	0/21 (0%)	0/5 (0%)	0/0 (0%)	0/0 (0%)

Not Available	0/0 (0%)	0/21 (0%)	0/5 (0%)	0/0 (0%)	0/0 (0%)

Notes:
1. Hemodynamic evaluations were performed using transthoracic echocardiography (TTE) and in some cases, transesophageal echocardiography (TEE).
2. MVR = Mitral valve replacement
3. DVR = Double valve replacement
4. Mean gradient in mm Hg.
5. EOA: Effective Orifice Area, cm^2
6. Regurgitation = none, 0; mild, 1+; moderate, 2+; moderate/severe, 3+; severe, 4+

8. INDIVIDUALIZATION OF TREATMENT

Bioprosthetic heart valve recipients should be maintained on anticoagulant therapy, except where contraindicated, during the initial stages after implantation as determined by the physician on an individual basis. Long-term anticoagulant and/or antiplatelet therapy should be considered for patients with a dilated left atrium, a history of thrombotic events, an absence of sinus rhythm, calcification of the atrial wall, or with atrial fibrillation or flutter.

The decision to use a tissue valve must ultimately be made by the physician on an individual basis after a careful evaluation of the short-term and long-term risks and benefits to the patient and consideration of alternative methods of treatment.

8.1. Specific Patient Populations

The safety and effectiveness of the Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis Model 6900 Mitral has not been established for the following specific populations because it has not been studied in these populations:

- patients who are pregnant;
- nursing mothers;
- patients with abnormal calcium metabolism (e.g., chronic renal failure or hyperparathyroidism);
- patients with aneurysmal aortic degenerative conditions (e.g., cystic medial necrosis or Marfan's syndrome);
- children, adolescents, or young adults.

9. PATIENT COUNSELING INFORMATION

Careful and continuous medical follow-up (at least by an annual visit to the physician) is advised so that valve-related complications, particularly those related to material failure, can be diagnosed and properly managed.

Patients with bioprostheses who are at risk of bacteremia (e.g., those undergoing dental procedures) should be advised about prophylactic antibiotic therapy.

10. HOW SUPPLIED

10.1. Packaging

The Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis Model 6900 Mitral is chemically sterilized and supplied sterile and non-pyrogenic in a glutaraldehyde storage solution. Sterility is compromised if the package is opened, damaged, or the plastic seal applied to the jar is broken. The outside of the container is NOT sterile.

> **Caution:** Do not use if the valve container is leaking, damaged, or the glutaraldehyde solution does not completely cover the bioprosthesis.

10.2. Storage

Storage between 10°C and 25°C (50°F and 77°F) is recommended. Do not freeze the bioprosthesis or expose it to extreme heat. Each jar is shipped in a molded foam enclosure that contains high- and low-temperature indicators attached to the interior of the enclosure. In the unactivated state, the center of each indicator is white. In the activated state, the center of each indicator turns black. If either temperature indicator has been activated (i.e., the center of the indicator is black), **do not use the bioprosthesis**. Immediately contact the local supplier or representative of Edwards Lifesciences to make arrangements for return and replacement. The molded foam and temperature indicators should be discarded after opening and inspecting, except in the case of an activated indicator.

The storage life of the Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis Model 6900 Mitral is four (4) years from the date of sterilization. Appropriate inventory control should be maintained so that bioprostheses with earlier expiration dates are preferentially implanted and expiration is avoided.

11. DIRECTIONS FOR USE

11.1. Physician Training

No special training is required to implant the Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis Model 6900 Mitral. The techniques for implanting these bioprostheses are similar to those used for any stented bioprosthesis.

11.2. Handling and Preparation Instructions

The bioprosthesis, the integral holder, and the glutaraldehyde solution are sterile. The outside of the jar is not sterile and must not be placed in the sterile field. The contents of the jar should be handled in an aseptic manner to prevent contamination.

Examine the lid seal to verify that the bioprosthesis container has not been damaged or previously opened. Remove the seal and turn the lid counter-clockwise to open the container. The bioprosthesis, retainer, and holder within the container are sterile.

> **Caution:** Do not use the bioprosthesis if it has been dropped, damaged, or mishandled in any way. Should a bioprosthesis be damaged during insertion, do not attempt repair.

Caution: Do not handle the tissue portion of the bioprosthesis with instruments or cause any damage to the valve tissue. Even the most minor tissue perforation may enlarge in time to produce significant impairment of valve function.

Using the sterile gloved hand or protected forceps, grasp the projecting tab of the plastic retainer. The leaflet tissue should never be handled. Remove the plastic retainer, the integral holder, and the valve from the jar as an assembly.

A tag with a serial number is attached to the sewing ring of each valve by a suture. This serial number should be checked against the number on the jar and implantation card; if any differences are noted, the valve should be returned unused. This tag should not be detached from the valve until just prior to implantation.

Verify that the handle, Model 1111 or 1126, has been sterilized as per the instructions provided in Section 11.5. If sterile, using handle Model 1111 or 1126, attach the handle to the valve by grasping the retainer at its outer edge as shown in Figure 2. **Do not grasp the valve.** Attach the handle by rotating the retainer or the handle. Tighten until positive contact is felt between the handle and holder. The three (3) commissures should deflect slightly towards the center of the valve as the handle is tightened.

An alternative method is to attach the handle to the valve holder while the valve is still in the container. To do this, simply insert the handle into the valve holder and turn it clockwise until it fits snugly. Be careful not to exert so much pressure while turning that the valve is pushed off the retainer ring and the tissue is damaged.

Once the handle has been attached, it should not be removed from the holder until after implantation has been completed and the handle/holder assembly has been detached as a unit and removed from the operating field.

Remove the retainer by grasping the retainer edge and tab together and pulling towards you at an angle (Figure 3). Discard the retainer.

Rinse Procedure

Within the sterile operative field, prepare three (3) rinse basins, each containing no less than 300 ml of sterile, physiological saline solution. Place the bioprosthesis in the saline solution and make sure that the solution completely covers the bioprosthesis and holder. With the valve and holder submerged, slowly agitate the basin (or use the attached handle to gently swirl the valve back and forth) for a minimum of 2 minutes in each of the three (3) previously prepared rinse basins. The bioprosthesis should remain in the third rinse basin until ready for implantation.

Caution: Avoid contact of the tissue or the rinse solution with towels, linens, or other sources of lint and particulate matter which may be transferred to the tissue.

Caution: Do not allow the tissue to contact the bottom or sides of the rinse basin.

Caution: Care must be taken to ensure that the serial number tag does not come in contact with the tissue during rinsing.

Inspection of the valve and removal of the serial number tag should be performed just prior to implantation. Care should be exercised to avoid cutting or tearing the suture ring cloth during removal of the serial number tag.

11.3. Device Implantation

Proper bioprosthesis size selection is an important part of heart valve replacement. Care must be exercised to avoid the use of too large a prosthesis since oversizing may create highly localized mechanical stresses resulting in tissue failure and valve regurgitation.

The size of the bioprosthesis to be used is determined using the Carpentier-Edwards TRUE-SIZE sizing obturator, Model 1162 mitral. Verify that the obturator has been sterilized as per the recommended instructions in Section 11.5. If sterile, insert the Model 1162 obturator into the mitral annulus. The obturator should fit snugly.

During implantation, the bioprosthesis should be periodically irrigated (every 1 to 2 minutes) with sterile physiological saline on both sides of the leaflet to prevent drying of the tissue.

Ensure proper orientation of the valve. The contrasting suture markers in the sewing ring should be oriented to straddle the ventricular outflow tract to obviate obstruction.

Caution: When using interrupted sutures, it is important to cut the sutures close to the knots to ensure that suture tails will not come into contact with the leaflet tissue.

Caution: Avoid looping or catching a suture around the open cages, free struts, or commissure supports of the valve which would interfere with proper valvular function.

The integral holder and attached handle are removed as a unit at the completion of the suturing procedure as follows (Figure 4):

1. Using a scalpel or scissors cut each of the three (3) exposed sutures that are on the surface of the holder. Avoid cutting or damaging the stent or leaflet tissue when cutting the sutures.

2. When all three (3) attaching sutures have been properly cut, remove the handle/holder assembly, along with attaching sutures, from the valve as a unit.

3. Following surgery, remove the holder from the handle and discard the holder.

11.4. Accessories

All accessories are supplied non-sterile, except for the integral holder which is supplied sterile attached to the sterile bioprosthesis.

Sizing Obturator

Use only the Carpentier-Edwards TRUE-SIZE sizing obturator (Model 1162 mitral) to determine the appropriate Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis Model 6900 Mitral size (Figure 5). Valve obturators permit direct observation of their fit within the annulus and are provided in the mitral configuration for each available bioprosthesis size.

> **Caution:** Do not use other manufacturer's valve obturators, or obturators for another Edwards Lifesciences prosthesis to size the Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis Model 6900 Mitral.

Valve Handle and Holder

The handle/holder assembly consists of two (2) components: the holder (an integral disposable part that is physically mounted to the valve by the manufacturer) and a handle (Model 1111 or 1126) that is attached to the holder at the time of surgery.

11.5. Accessory sterilization

Handles and obturators are supplied non-sterile and must be sterilized before using. The handles and sizing obturators must be disassembled, cleaned, and re-sterilized prior to each use. Obturators should be examined for signs of wear, such as dullness, cracking, or crazing, and should be replaced if any deterioration is observed.

> **Caution:** Do not sterilize the obturators and handles in their shipping containers.

The accessories can be sterilized using the following recommended autoclave sterilization methods:

I. Gravity Displacement

a) Wrapped:
Temperature: 270°-275°F (132°-135°C)
Exposure Time: 10-15 minutes

b) Un-wrapped ("flash"):
Temperature: 270°F (132°C)
Exposure Time: 3 minutes

II. Prevacuum

a) Wrapped:
Temperature: 270°-275°F (132°-135°C)
Exposure Time: 3-4 minutes

b) Un-wrapped ("flash"):
Temperature: 270°F (132°C)
Exposure Time: 3 minutes

Each institution should use procedures that include biological indicators to determine the effectiveness of the sterilization procedure.

11.6. Return of Explanted Bioprostheses

Edwards Lifesciences is interested in obtaining recovered Carpentier-Edwards PERIMOUNT Pericardial Brioprostheses Model 6900 Mitral. Specific studies will be performed and a written report of our findings will be provided to the physician upon completion of our evaluation. Please contact your Edwards Lifesciences local valve specialist for information on the procedures to follow to return an explanted Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis Model 6900 Mitral. It is important that the explant be placed in a container of 10% formalin or 2% glutaraldehyde immediately after excision. Refrigeration is not necessary under these circumstances.

12. PATIENT INFORMATION

12.1. Registration Information

An *Implantation Data Card* is included in each device package for patient registration. After implantation, please complete all requested information. The valve serial number is listed on the valve packaging and on the identification tag attached to the bioprosthesis, and is pre-printed on the *Implantation Data Card*. Return the pre-addressed portion of the card to our Implant Patient Registry. The remaining portions of the card are provided for hospital and surgeon records. Upon receipt by our Implant Patient Registry, a wallet-sized identification card will be produced for the patient. This card allows patients to inform healthcare providers what type of implant they have when they seek care. When a valve is discarded or a previous Edwards Lifesciences device is replaced, report such events to our Implant Patient Registry.

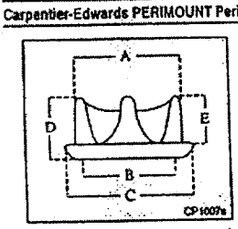
12.2. Patient Manual

Patient information materials may be obtained from Edwards Lifesciences or an Edwards Lifesciences valve specialist.

Figure 1

Nominal Specifications

Carpentier-Edwards PERIMOUNT Pericardial Valve, Model 6900



Size	25 mm	27 mm	29 mm	31 mm	33 mm
A. Mounting Diameter (Annulus)* (mm)	25	27	29	31	33
B. Internal Diameter** (mm)	23	25	27	29	31
C. External Sewing Ring Diameter (mm)	35	37	39	41	43
D. Total Profile Height (mm)	17	18	19	20	20
E. Ventricular Projection (mm)	12	12	13	15	15
F. Calculated Internal Orifice Area (cm^2)	4.2	4.9	5.7	6.6	7.5

* Mounting diameter (annulus) = portion of the sewing ring intended to seat within the patients's annulus.
** Orifice diameter = inside diameter of cloth covered stent.

Figure 2

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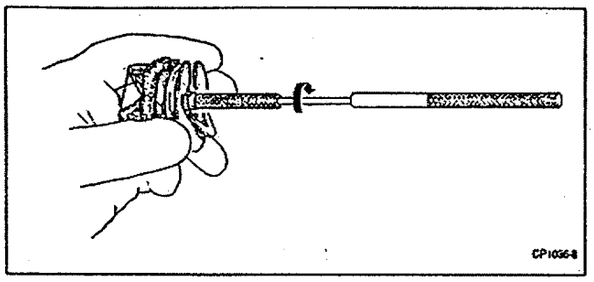


Figure 3

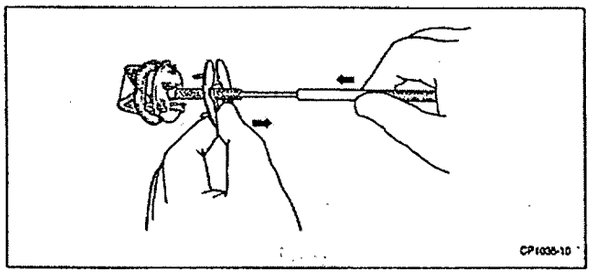


Figure 4

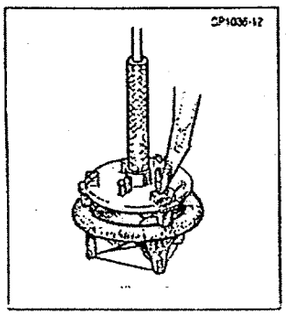
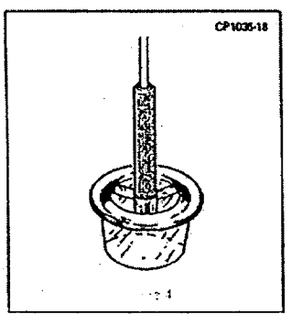


Figure 5



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This product is manufactured and sold under one or more of the following US patent(s): US-Patent Nos. 4,501,030; 4,885,005; 5,961,549, and corresponding foreign patents. Additional patents are pending.

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