Edwards Prima Plus Stentless Bioprosthesis Model 2500P
Instructions for Use

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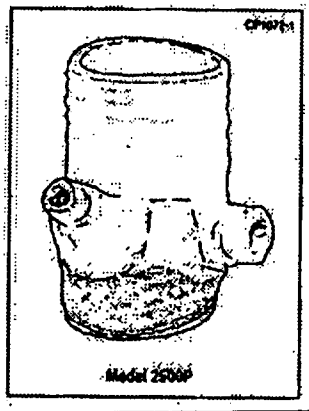

Instructions for Use

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

1. DEVICE DESCRIPTION

The Edwards Prima Plus Stentless Bioprosthesis Model 2500P is a porcine valve aortic root cylinder that has been preserved in a buffered glutaraldehyde solution. 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 Edwards Prima Plus Stentless Bioprosthesis Model 2500P is designed for the aortic position and is available in the following implantation diameters: 21, 23, 25, and 27 mm.

Woven polyester cloth is sewn with green suture around the inflow annulus to give additional support to the first suture line. Green marking sutures midway around the intercommissural periphery aid in the placement of stitches around the annulus. Black marking sutures at the mid-commissural positions on the inflow rim aid in proper alignment with the patient's anatomy. A green trim guide placed externally on the valve wall indicates the recommended limit for trimming the valve for subcoronary implantation while maintaining adequate tissue for placement of the second suture line.

2. INDICATIONS FOR USE

The Edwards Prima Plus Stentless Bioprosthesis Model 2500P is indicated for patients who require replacement of their native or prosthetic aortic valve using the subcoronary implantation technique.

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 (2) temperature indicators, which are intended for monitoring the temperature that the device is exposed to during transit. If either indicator has been activated, do not use the valve.

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, 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, etc., 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 it may cause tissue damage.
- Adequate removal of calcium deposits from the patient's annulus must be performed before implantation to avoid damage to the delicate prosthetic valve leaflet tissue as a result of contact with calcium deposits.
- 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.
- Do not use the valve if it has been dropped, damaged, or mishandled in any way. Should a bioprosthesis be damaged during insertion, do not attempt repair.

- Do not handle the leaflet tissue 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.

6. ADVERSE EVENTS

6.1. Observed Adverse Events

Two multi-center, non-randomized, prospective clinical studies were conducted. The first study was a long-term evaluation of 160 patients implanted with the Edwards Prima Stentless Bioprosthesis Model 2500 in the subcoronary configuration and was conducted between 1991 and 1999. The second study was a short-term evaluation of 206 patients implanted with the Edwards Prima Plus Stentless Bioprosthesis Model 2500P in the subcoronary configuration and was conducted between 1998 and 2000. In the long-term study, patients were evaluated preoperatively, intraoperatively/at discharge, at 3 to 6 months, at 1 year, and annually thereafter. In the short-term study, patients were evaluated preoperatively, intraoperatively/at discharge, at 3 to 6 months, and at 1 year. Adverse events were captured throughout the postoperative period.

Table 1 presents the observed rates for early events (≤ 30 days for valve-related adverse events), the linearized rates for late events (>30 days postoperatively), and the cumulative freedom from adverse event rates at 1, 5, and 8 years postoperatively. The adverse event rates were based on 366 patients at 13 centers, with one center participating in both the long-term and short-term studies. The cumulative follow-up was 1074.2 patient-years with a mean follow-up of 2.9 years (SD=2.9 years, range=0 to 8.2 years).

Table 1: Observed Adverse Event Rates for AVR (Subcoronary Implant)
All patients analyzed: N= 366 Cumulative follow-up: 1074.2 patient-years

	Early Events		Late Events[1]		Freedom from Event (%) ± 95% CI[2]		
Complication	n[3]	%	n	%/pt.-yr.	1 year (n = 366)	5 years (n = 134)	8 years (n = 56)
Mortality (all)	12	3.3	42	4.0	94.6 ± 2.9	81.3 ± 6.3	66.6 ± 37.7
Valve-related mortality	2	0.5	18	1.7	98.3 ± 1.7	93.1 ± 4.4	87.0 ± 30.7
Explant	0	0.0	6	0.6	99.6 ± 0.8	96.9 ± 3.0	95.1 ± 20.6
Reoperation[4]	0	0.0	0	0.0	100 ± 0.0	100 ± 0.0	100 ± 0.0
Bleeding	7	1.9	9	0.9	95.2 ± 2.8	95.2 ± 2.8	93.5 ± 27.1
Endocarditis	0	0.0	9	0.9	99.2 ± 1.2	94.5 ± 4.0	94.5 ± 21.7
Hemolysis	0	0.0	0	0.0	100 ± 0.0	100 ± 0.0	100 ± 0.0
Nonstructural dysfunction[5]	5	1.4	9	0.9	96.1 ± 2.6	96.1 ± 3.6	96.1 ± 26.4
Perivalvular leak	5	1.4	8	0.8	96.5 ± 2.5	96.5 ± 3.4	96.5 ± 25.1
Structural valve deterioration	0	0.0	11	1.1	100 ± 0.0	96.0 ± 3.4	86.8 ± 30.9
Thromboembolism	12	3.3	28	2.7	95.8 ± 2.7	84.8 ± 6.2	82.7 ± 38.9
Valve thrombosis	0	0.0	0	0.0	100 ± 0.0	100 ± 0.0	100 ± 0.0

Notes:
1. Late event rates were calculated as linearized rates (%/pt-yr) based on 1044.3 late patient-years (>30 days postoperatively).
2. Freedom from event rates were calculated using the Kaplan-Meier method. Peto's formula was used for calculation of the 95% confidence intervals.
3. n = number of patients
4. Includes reoperation without valve explant.
5. Nonstructural dysfunction includes perivalvular leak. All operative nonstructural dysfunction events were perivalvular leaks.

6.2. Potential Adverse Events

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

- death
- endocarditis
- hemolysis
- hemorrhage, anticoagulant/antiplatelet-related leak, transvalvular, or perivalvular
- nonstructural dysfunction (hemolysis, perivalvular leak, pannus, entrapment by suture, inappropriate sizing, or other)
- structural deterioration (calcification, leaflet tear or other)
- thromboembolism
- valve thrombosis
- reoperation
- explant

Other adverse events associated with the use of the Edwards Prima Stentless Bioprosthesis Model 2500 and/or the Edwards Prima Plus Stentless Bioprosthesis Model 2500P compiled from the literature and from reports received through Edwards Lifesciences complaint handling system include: stenosis, regurgitation through an incompetent valve, malfunctions of the valve due to distortion at implant, or physical or chemical deterioration of valve components.

7. CLINICAL STUDIES

The safety endpoints captured in the prospective studies were complications; blood analyses were used to confirm the absence or presence of hemolysis, hemolytic anemia, and endocarditis. 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. There were insufficient clinical data to support the safety and effectiveness of this device for root inclusion or full root implantation.

Table 2: Preoperative Patient Demographics

Variable	Category	Study Results (N=366; 1074.2 total pt-yrs.)	
		n	% (n/N)[1]
Age at implant	Mean ± SD	366	70.2 ± 7.1
Gender	Male	217	59.3%
	Female	149	40.7 %
NYHA Classification	I	23	6.3%
	II	138	37.7%
	III	177	48.4%
	IV	25	6.8%
	Not reported	3	0.8%
Diagnosis	Stenosis	243	66.4%
	Regurgitation	27	7.4%
	Mixed Disease	94	25.7%
	Malfunctioning prosthesis	2	0.5%

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

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Table 3: Operative Patient Demographics

Variable	Category	Study Results (N=366; 1074.2 total pt-yrs.)	
		n	% (n/N)[1]
Etiology[2]	Calcification/degeneration	297	81.1%
	Rheumatic heart disease	33	9.0%
	Congenital abnormalities	31	8.5%
	Other[3]	6	1.6%
Concomitant Procedures[2]	None	230	62.8%
	CABG[4]	122	33.3%
	AAA[5] repair	5	1.4%
	Mitral valve repair	3	0.8%
	Mitral valve replacement	1	0.3%
	Other[6]	8	2.2%
Pre-existing Conditions[2]	None	143	39.1%
	TIA/CVA[7]	26	7.1%
	Congestive Heart Failure	36	9.8%
	Arrhythmias	37	10.1%
	Systemic Hypertension	88	24.0%
	CAD[8]/CABG	133	36.3%
Valve Size (mm)	19	7	1.9%
	21	47	12.8%
	23	85	23.2%
	25	123	33.6%
	27	81	22.1%
	29	23	6.3%

Notes:
1. n = number of patients in each category; N = total number of study patients
2. May be more than one per patient
3. Includes previously failed prosthesis, root dilatation, and ischemic disease
4. CABG = Coronary Artery Bypass Graft
5. AAA=Abdominal Aortic Aneurysm
6. Includes carotid endarterectomy, fistula exploration, ventricular septal defect repair, aortotomy, intra-aortic balloon pump, tumorectomy, and interatrial septum exploration
7. TIA = Transient ischemic attack. CVA = Cerebrovascular accident.
8. CAD = Coronary Artery Disease

Table 4: Effectiveness Outcomes, Functional NYHA

NYHA Functional Class	Preoperative Assessment		Postoperative Assessments			
			1 Year		4 to 5 Years	
	n/N[1]	%	n/N	%	n/N	%
I	17/313	5.4%	184/250	73.6%	58/160	36.3%
II	119/313	38.0%	23/250	9.2%	37/160	23.1%
III	156/313	49.8%	3/250	1.2%	8/160	5.0%
IV	21/313	6.7%	0/250	0.0%	1/160	0.6%
Not Available	0/313	0.0%	40/250	16.0%	56/160	35.0%

Notes:
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					
	19mm	21mm	23mm	25mm	27mm	29mm
Discharge (n=312)						
Mean gradient[2]	n = 7	n = 41	n = 68	n = 95	n = 69	n = 20
• mean ± sd	15.4 ± 7.4	15.9 ± 7.5	13.5 ± 5.6	10.7 ± 5.4	9.5 ± 5.3	7.0 ± 5.2
• min, max	6.0, 24.0	4.0, 37.0	2.0, 28.0	1.0, 34.0	1.0, 30.0	1.0, 21.0
EOA[3]	n = 6	n = 37	n = 62	n = 80	n = 55	n = 16
• mean ± sd	1.05 ± 0.32	1.17 ± 0.33	1.35 ± 0.37	1.68 ± 0.60	1.87 ± 0.54	2.71 ± 1.64
• min, max	0.70, 1.45	0.50, 1.96	0.64, 2.26	0.89, 4.61	1.15, 3.60	1.20, 8.19
Regurgitation[4]	n = 7	n = 43	n = 70	n = 98	n = 72	n = 21
0	7 (100%)	33 (76.7%)	45 (64.3%)	66 (67.3%)	50 (69.4%)	18 (85.7%)
1+	0 (0.0%)	9 (20.9%)	17 (24.3%)	25 (25.5%)	13 (18.1%)	1 (4.8%)
2+	0 (0.0%)	1 (2.3%)	8 (11.4%)	6 (6.1%)	7 (9.7%)	2 (9.5%)
3+	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)
4+	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Not available	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.8%)	0 (0.0%)
1 Year (n=203)						
Mean gradient[2]	n = 7	n = 24	n = 46	n = 72	n = 45	n = 5
• mean ± sd	17.8 ± 9.0	14.5 ± 6.4	11.5 ± 8.7	9.5 ± 5.8	6.7 ± 3.0	4.4 ± 2.7
• min, max	6.3, 31.0	5.0, 29.0	2.0, 55.9	1.9, 29.0	2.0, 17.0	1.5, 8.0
EOA[3]	n = 7	n = 21	n = 44	n = 61	n = 37	n = 4
• mean ± sd	0.88 ± 0.20	1.20 ± 0.48	1.43 ± 0.43	1.74 ± 0.53	2.04 ± 0.62	2.64 ± 0.56
• min, max	0.68, 1.30	0.76, 2.50	0.60, 2.64	0.80, 3.70	0.76, 3.42	2.12, 3.22
Regurgitation[4]	n = 7	n = 26	n = 48	n = 74	n = 45	n = 5
0	5 (71.4%)	16 (61.5%)	29 (60.4%)	45 (60.8%)	28 (62.2%)	3 (60.0%)
1+	2 (28.6%)	9 (34.6%)	11 (22.9%)	17 (23.0%)	15 (33.3%)	1 (20.0%)
2+	0 (0.0%)	0 (0.0%)	8 (16.7%)	11 (14.9%)	2 (4.4%)	1 (20.0%)
3+	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)
4+	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Not available	0 (0.0%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
4 To 5 Years (n=112)						
Mean gradient[2]	n = 2	n = 13	n = 26	n = 38	n = 21	n = 1
• mean ± sd	27.9 ± 5.8	15.9 ± 7.0	9.9 ± 5.7	8.8 ± 4.9	6.5 ± 3.9	4.2
• min, max	23.8, 32.0	5.5, 32.2	3.0, 23.2	1.3, 23.0	1.0, 14.0	4.2, 4.2
EOA[3]	n = 1	n = 12	n = 23	n = 30	n = 16	n = 0
• mean ± sd	1.00	1.10 ± 0.36	1.60 ± 0.51	1.91 ± 0.36	2.06 ± 0.58	–
• min, max	1.00, 1.00	0.20, 1.68	0.47, 2.60	0.93, 4.06	1.20, 3.20	–
Regurgitation[4]	n = 5	n = 17	n = 31	n = 41	n = 21	n = 1
0	4 (80.0%)	11 (64.7%)	17 (54.8%)	24 (58.5%)	17 (81.0%)	0 (0.0%)
1+	0 (0.0%)	6 (35.3%)	9 (29.0%)	12 (29.3%)	2 (9.5%)	0 (0.0%)
2+	0 (0.0%)	0 (0.0%)	4 (12.9%)	1 (2.4%)	1 (4.8%)	1 (100%)
3+	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)
4+	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Not available	1 (20.0%)	0 (0.0%)	1 (3.2%)	4 (9.8%)	0 (0.0%)	0 (0.0%)

Notes:

1. Hemodynamic evaluations were performed using transthoracic echocardiography (TTE).
2. Mean gradient in mm Hg.
3. EOA: Effective Orifice Area, cm^2
4. Regurgitation: 0 = none; 1+ = trivial; 2+ = mild; 3+ = moderate; 4+ = severe

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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 Edwards Prima Plus Stentless Bioprosthesis Model 2500P 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, hyperparathyroidism);
- patients with aneurysmal aortic degenerative conditions (e.g., cystic medial necrosis, 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 are at risk of bacteremia (e.g., undergoing dental procedures) should be advised about prophylactic antibiotic therapy.

10. HOW SUPPLIED

10.1. Packaging

The Edwards Prima Plus Stentless Bioprosthesis Model 2500P 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 and 77°F) is recommended. Do not freeze the bioprosthesis or expose 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 inactivated 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 Edwards Prima Plus Stentless Bioprosthesis Model 2500P 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

The Edwards Prima Plus Stentless Bioprosthesis Model 2500P is modified at surgery for implant using the subcoronary technique. The techniques for implanting these bioprostheses in the subcoronary configuration are similar to those used for homografts or other stentless bioprostheses.

11.2. Handling and Preparation Instructions

Proper bioprosthesis size selection is an important part of the heart valve replacement. Size of the Edwards Prima Plus Stentless Bioprosthesis Model 2500P is determined using Edwards sizing sizers, Model 1170.

> **Caution:** The valve accessories (sizer or handle) should not be used unless cleaned and sterilized as per the instructions in Section 11.5.

The bioprosthesis, 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 valve 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 leaflet tissue 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 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 has been sterilized as per the instructions provided in Section 11.5. If sterile, using handle Model 1111 or Model 1126, attach the handle to the valve by grasping the retainer at its outer edge as shown in Figure 1. **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.

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.

Remove the retainer by grasping the retainer edge and tab together and pulling towards you at an angle (Figure 2). Discard the retainer.

Rinse Procedure

Within the sterile operative field, prepare three rinse basins, each containing no less than 750 ml of sterile, physiological saline solution. Place the bioprosthesis in the saline solution and make sure that it 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 1 minute in each of the three 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 that 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.

The integral holder and attached handle may be removed as a unit at the completion of the rinsing procedure as follows (Figure 3):

1. Using a scalpel or scissors cut each of the two exposed sutures that are on the surface of the holder. Avoid cutting or damaging the valve tissue when cutting the sutures.
2. When the attaching sutures have been properly cut, remove the handle/holder assembly, along with attaching sutures, from the valve as a unit.
3. Remove the holder from the handle and discard the holder.

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 to prevent folding or extreme deformation of the valve that may render it incompetent. Inappropriate sizing may create highly localized mechanical stresses resulting in tissue failure in the form of excessive wear of the leaflets or detachment of the leaflets or porcine aortic wall from the patient's aorta.

Size of the bioprosthesis is determined using the Edwards sizing sizer, Model 1170. Verify that the sizer and handle (Model 1111 reusable handle or Model 1126 single use handle) have been sterilized as per the recommended instructions in Section 11.5. If sterile, insert the handle into the sizer and turn it clockwise until positive contact is felt between the handle and sizer (Figures 5 and 6). Insert the Model 1170 sizer into the aortic annulus. The sizer 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.

Surgeons implanting the Edwards Prima Plus Stentless Bioprosthesis Model 2500P should be experienced in the implantation techniques required for subcoronary implantation (e.g., prior homograft implantation experience or other appropriate knowledge and experience). In general, the following steps should be used for implantation of the Edwards Prima Plus Stentless Bioprosthesis Model 2500P:

1. Surgically remove the diseased or damaged leaflets and all associated structures deemed necessary by the surgeon.

2. Surgically remove any calcium from the annulus and extension of the anterior leaflet of the mitral valve to ensure proper suture placement and positioning of the valve.

3. Select the appropriate size bioprosthesis, using only Edwards Model 1170 sizing sizers.

4. Rinse the bioprosthesis according to the instructions in the **Rinse Procedure** section above.

5. Trim the bioprosthesis for subcoronary implantation. The green trim guide placed externally on the aortic wall of the bioprosthesis marks the recommended limit of safe trimming for subcoronary implantation.

6. Suture the bioprosthesis in place using an appropriate suturing technique.

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

11.4. Accessories

All accessories are supplied non-sterile, except for the integral holder that is supplied sterile attached to the sterile bioprosthesis, and the Model 1126 single use handle that is supplied sterile and is intended for single use only. A tray for organizing the sizers and handles is available (Tray 1170).

Sizing Sizer

Use only the Edwards sizing sizer (Model 1170) with attached handle to determine the appropriate Edwards Prima Plus Stentless Bioprostheses Model 2500P size (Figures 4 and 5). Valve sizers are transparent gray in color and permit direct observation of their fit within the annulus. Sizers are provided for each available bioprosthesis size.

> **Caution:** Do not use other manufacturers' valve sizers, or sizers for another Edwards Lifesciences prosthesis to size the Edwards Prima Plus Stentless Bioprostheses Model 2500P.

Valve Handle and Holder

The handle/holder assembly consists of two components: the holder (an integral disposable part that is physically mounted to the valve by the manufacturer) and a handle (Model 1111 reusable handle or Model 1126 single use handle) that is attached to the holder at the time of surgery. The Model 1126 handle and the middle portion of the Model 1111 handle are malleable, allowing the handle to be adjusted (bent) in a configuration convenient for use.

> **Caution:** Only minor adjustments should be made in the Model 1111 handle after the initial bend. Repeated straightening and bending will eventually cause the handle to break.

11.5. Accessory Cleaning and Sterilization

The Model 1126 handle is supplied sterile and is for single use only. The Model 1111 reusable handle and the Model 1170 sizers are supplied non-sterile and must be sterilized before using. Clean the organizational tray and lid (Model tray 1170) separately prior to each use. The handle and sizing sizers must be disassembled, cleaned, and re-sterilized prior to each use. Sizers 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 sizers or handles in their shipping containers.

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

I. Gravity Displacement

a) Wrapped:
Temperature: 270°-279°F (132°-137°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°-279°F (132°-137°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 Edwards Prima Plus Stentless Bioprostheses Model 2500P. 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 clinical sales specialist for information on the procedures to follow to return an explanted Edwards Prima Plus Stentless Bioprosthesis Model 2500P. 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 this information to our Implant Patient Registry.

12.2. Patient Manual

Patient information materials may be obtained from Edwards or an Edwards clinical sales specialist.

Specifications

Significant dimensions in mm (nominal values)				
Edwards Prima Plus Stentless Bioprosthesis Model 2500P				
Bioprosthesis Size	21	23	25	27
Valve Mounting Diameter (Annulus)*	21	23	25	27
Fixation pressure: Low pressure (approx. 2 mmHg)				
Fixation solution: 0.625% w/v buffered glutaraldehyde				

*Mounting diameter (annulus) = outside diameter of the porcine graft measured at the inflow annulus

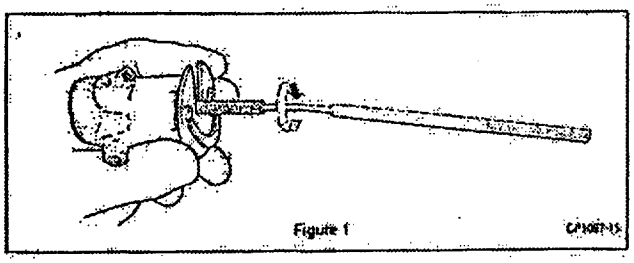


Figure 1

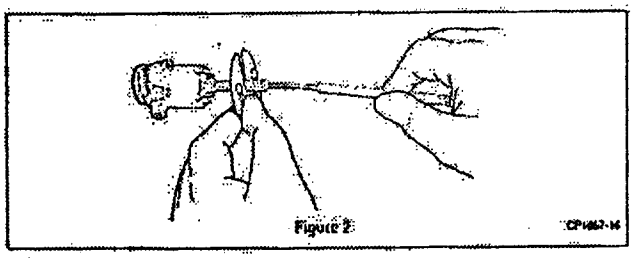
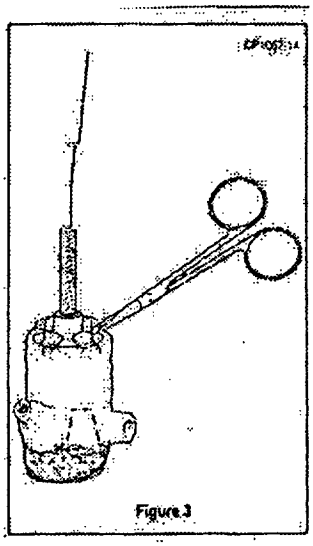


Figure 2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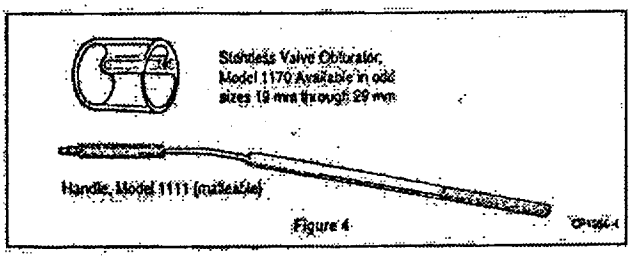

Figure 4

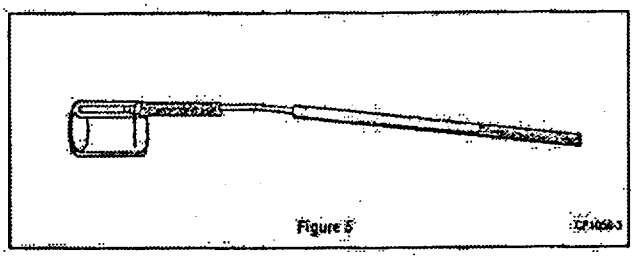
Figure 5

Prices subject to change without notice. This product is manufactured and sold under one or more of the following US patents: US-Patent Nos. 4,885,005; 5,197,979; 5,336,258; 6,001,126, and corresponding foreign patent applications. Additional patents are pending.

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