Carpentier-Edwards PERIMOUNT Magna Mitral Ease Pericardial Bioprosthesis Model 7300TFX

A PERI valve

Instructions for Use

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

1.0 Device Description

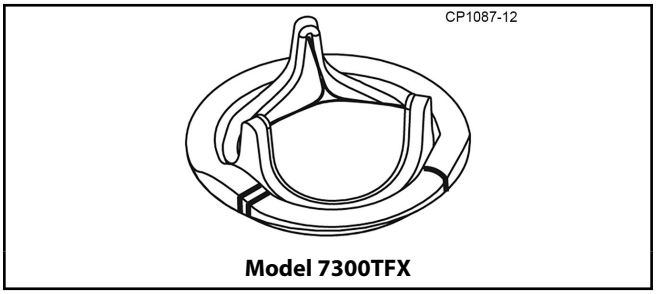
The Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprosthesis is built upon the same proven (Ref. 1) wireform frame and leaflet attachment as the PERIMOUNT mitral pericardial bioprostheses models 6900, 6900P, 6900PTFX, and 7000TFX. It is available in the sewing ring diameters and sizes shown in Figure 1. The bioprosthesis incorporates a sewing ring specifically designed for the mitral position and is the first bioengineered mitral bioprosthesis design with three selected bovine pericardial leaflets mounted on a flexible metal alloy frame.

Bovine pericardium was selected for its superior intrinsic properties for valve manufacture, notably in terms of collagen content (Ref. 2) and tolerance to high bending curvatures (Ref. 3). Bovine pericardium tissue is cross-linked using the Neutralogic fixation process in which the tissue is placed in a stress-free bath of buffered glutaraldehyde solution. The bioprosthesis is treated according to the ThermaFix process, which involves heat treatment of the tissue in glutaraldehyde and uses ethanol and Polysorbate-80 (a surfactant). Glutaraldehyde is shown to both reduce the antigenicity of tissue xenograft valves and increase tissue stability (Refs. 4 & 5). Glutaraldehyde alone has not been shown to affect or reduce the calcification rate of the valve.

Tissue thickness is measured for each valve size and leaflets are precisely die-cut in selected areas of a pericardial sheet. Leaflet deflection testing characterizes each leaflet for elasticity. Three leaflets matched for similar thickness and elasticity are then assembled. Leaflets are mounted underneath the wireform frame to minimize commissural stress points.

The lightweight wireform frame is made of a corrosion-resistant cobalt- chromium alloy, chosen because of its superior spring efficiency and fatigue resistance characteristics. The frame is designed to be compliant at the orifice as well as at the commissures. The frame is covered with a woven polyester fabric sewn with polytetrafluoroethylene thread. The wireform frame of the Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis is symmetrical and the three commissure supports (struts) are equally spaced.

A cobalt-chromium alloy band attached to a polyester film band surrounds the base of the wireform frame providing structural support for the orifice and allows for radiological identification. In addition to maintaining the orifice shape during implantation, the band serves as a point of attachment for the sewing ring.



Model 7300TFX

The sewing ring is made of waffled silicone-rubber and is covered with a porous polytetrafluoroethylene cloth sewn with polytetrafluoroethylene thread. The cloth facilitates tissue in-growth and encapsulation. The sewing ring of the Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis is uniquely scalloped along its anterior portion and mimics the natural saddle shape of the native mitral valve anatomy. Black silk suture markers on the anterior portion facilitate the orientation of the bioprosthesis and help avoid obstruction of the left ventricular outflow tract by a strut. A black silk suture guide line circles the sewing ring. Placing sutures through the sewing ring and in the region from the suture guide line to the outer portion of the sewing ring complements the design of the silicone waffle by easing needle penetration and providing variable compliance. The waffle has wider cells along the posterior portion, where calcifications or irregularities of the native mitral annulus are more frequent (Ref. 6). This results in a very compliant sewing ring that facilitates coaptation between the sewing ring and the mitral tissue bed. The width of the sewing ring allows for coverage of an irregular or calcified mitral annulus.

The Tricentrix holder system is designed to minimize the potential for suture or chordae entrapment, ease insertion and increase leaflet visibility. The holder consists of three main components: a grey holder, a white holder post, and a blue adapter. It is secured to the bioprosthesis with green sutures. The bioprosthesis and holder attachment are suspended by a clip and a sleeve within a sealed jar that contains a glutaraldehyde packing solution. The bioprosthesis is terminally sterilized in glutaraldehyde.

2.0 Indications for Use

The Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprosthesis model 7300TFX is indicated for patients who require replacement of their native or prosthetic mitral valve.

3.0 Contraindications

Do not use if the surgeon believes such would be contrary to the best interests of the patient. The actual decision for or against the use of this bioprosthesis must remain with the surgeon who can evaluate all the various risks involved, including the anatomy and pathology observed at the time of surgery.

4.0 Warnings

FOR SINGLE USE ONLY. This device is designed, intended, and distributed for single use only. Do not re-sterilize or reuse this device. There are no data to support the sterility,

nonpyrogenicity, and functionality of the device after reprocessing. 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 BIOPROSTHESIS TO EXTREME HEAT. Exposure of the bioprosthesis to extreme temperatures will render the device unfit for use. Please refer to Packaging section (10.2) for further instructions.

DO NOT USE the bioprosthesis if the tamper evident seal on the jar is broken.

DO NOT USE the bioprosthesis if expiration date has elapsed.

DO NOT USE the bioprosthesis if the container is leaking, damaged, or the glutaraldehyde solution does not completely cover the bioprosthesis.

DO NOT EXPOSE the bioprosthesis to any solutions, chemicals, antibiotics, etc., except for the storage solution or sterile physiological saline solution. Irreparable damage to the leaflet tissue, which may not be apparent under visual inspection, may result.

DO NOT ALLOW the bioprosthesis 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 bioprosthesis with the exception of a surgical mirror used to examine struts and suture placement. Other surgical devices may cause leaflet tissue damage.

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.

DO NOT GRASP the leaflet tissue of the bioprosthesis with instruments or cause any damage to the bioprosthesis. Even the most minor leaflet tissue perforation may enlarge in time to produce significant impairment of valve function.

DO NOT OVERSIZE. Oversizing may cause bioprosthesis damage or localized mechanical stresses, which may in turn injure the heart or result in leaflet tissue failure, stent distortion and valve regurgitation.

Clinical data that establish the safety and efficacy of the bioprosthesis for use in patients under the age of 20 are not available; therefore, we recommend careful consideration of its use in younger patients. As with any implanted medical device, there is a potential for patient immunological response (see device description for materials).

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

Long-term durability has not been established for bioprostheses. Serious adverse events, sometimes leading to replacement of the bioprosthesis and/or death, may be associated with the use of prosthetic valves (see **6.0 Adverse Events**). A full explanation of the benefits and risks should be given to each prospective patient before surgery.

Note: Bioprostheses should be used with caution in the presence of severe systemic hypertension or when the anticipated patient longevity is longer than the known longevity of the prosthesis (see 7.0 Clinical Studies). Careful and continuous medical follow-up (at least by an annual visit to the physician) is advised so that bioprosthesis-related complications, particularly those related to material failure, can be diagnosed and properly managed.

Recipients of prosthetic heart valves who are undergoing dental procedures should receive prophylactic antibiotic therapy to minimize the possibility of prosthetic infection. Bioprosthetic heart valve recipients should be maintained on anticoagulant therapy (except where contraindicated) during the initial healing stages after implantation, approximately 2 to 3 months. Anticoagulants should then be discontinued over a period of 10 days, except in those patients for whom indefinite anticoagulant protection is indicated, i.e., in the absence of sinus rhythm and in patients with a dilated left atrium, calcification of the atrial wall, or history of previous atrial thrombus. However, the appropriate anticoagulation therapy must be determined by the physician on an individual basis (Ref. 7).

Adequate rinsing with physiological saline is mandatory before implantation to reduce the glutaraldehyde concentration (see **11.4 Handling and Preparation Instructions**). No other solutions, drugs, chemicals, antibiotics, etc., should ever be added to the glutaraldehyde or rinse solutions, as irreparable damage to the leaflet tissue, which may not be apparent under visual inspection, may result.

5.0 Precautions

- Do not sterilize the sizer models 1173B, 1173R and handle models 1111, 1117, or 1173 in their shipping containers.
- Use only the sterilization tray provided in model SET1173 to sterilize the sizers and the handles.
- The outside of the jar is not sterile and must not be placed in the sterile field.
- To avoid contamination, it is strongly recommended that the jar of a Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprosthesis model 7300TFX not be opened unless implantation is certain.
- Adequate rinsing with physiological saline must be performed before implantation to reduce the glutaraldehyde concentration.
- Avoid contact of the leaflet tissue or the rinse solution with towels, linens, or other sources of lint and particulate matter that may be transferred to the leaflet tissue.
- Do not allow the leaflet tissue to contact the bottom or sides of the rinse basin.
- 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 available from Edwards Lifesciences.
- Always deploy the Tricentrix holder system fully to minimize the risk of suture entrapment. It will snap into a secured and locked position.
- A serial number tag is attached to the sewing ring of each bioprosthesis by a suture. This serial number should be checked against the number on the jar and implantation data card; if any difference is noted, the bioprosthesis should be returned unused. Care must be taken to ensure that the serial number tag does not come in contact with the leaflet tissue during rinsing. Inspection of the bioprosthesis and removal of the serial number tag should be performed just prior to implantation. Care should be exercised to avoid cutting or tearing the sewing ring cloth during removal of the serial number tag.
- Careful handling is required for all implantable devices. If the bioprosthesis is dropped, damaged, or mishandled in any way, it must not be used for human implantation.
- To avoid damage to the delicate bioprosthetic leaflet tissue, as a result of contact with calcium deposits, adequate removal

of calcium deposits from the patient's annulus must be performed before implantation.

- Handle the bioprosthesis only with Edwards Lifesciences accessories. Only Edwards Lifesciences sizers model 1173B or 1173R should be used during the selection of the Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis size; other sizers may result in improper bioprosthesis selection.
- Oversizing must be avoided as it may cause bioprosthesis damage or localized mechanical stresses, which may in turn injure the heart or result in leaflet tissue failure, stent distortion and regurgitation.
- Special care must be exercised when using chordal preservation techniques to avoid chordae entrapment by a strut.
- Due to the relative flexibility of the frame, care must be exercised to prevent folding or deformation of the stent.
- The surgeon should be familiar with the recommendations for proper sizing and placement of the bioprosthesis according to the suture technique used (see **11.5 Device Implantation**).
- The sewing ring is designed for a specific orientation: the scalloped part of the sewing ring, between the black suture markers, should be placed across the intercommissural anterior portion of the annulus and straddle the left ventricular outflow tract.
- Special care must be exercised to avoid placing a strut in front of the left ventricular outflow tract, as this may impair the long-term hemodynamic performance.
- As with all prostheses that have open cages, free struts, or commissure supports, care must be exercised to avoid looping or catching a suture around a commissure, which would interfere with proper valvular function. To minimize the potential for suture looping, it is essential to leave the deployed holder in place until all knots are tied.
- If the deployed holder attachment threads are cut before all the sutures adjacent to the struts are tied down, the holder will no longer minimize the potential for suture looping.
- 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.

6.0 Adverse Events

6.1 Observed Adverse Events

The Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprosthesis model 7300TFX uses the same wireform frame and leaflet attachment as Edwards Lifesciences pericardial mitral bioprostheses models 6900, 6900P, 6900PTFX, and 7000TFX. Three (3) multi-center, non-randomized, prospective non-US clinical studies were conducted with the mitral pericardial bioprosthesis model 6900. 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 PERIMOUNT pericardial bioprosthesis aortic model. In the first study, bioprostheses were implanted between 1984 and 1986; in the second study, bioprostheses were implanted between 1989 and 1994; and in the third study, bioprostheses were implanted 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 for valve-related adverse events), the linearized rates for late events (> 30 days postoperatively), and the actuarial adverse event rates at 1, 5, and 8 years postoperatively for model 6900. The adverse event rates were based on 363 patients at nine 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). Preoperative and operative patient demographics are presented in Tables 3 and 5. Effectiveness results are presented in Tables 7 and 9.

One (1) multi-center, non-randomized, prospective international clinical study was conducted with patients implanted with the Carpentier-Edwards PERIMOUNT Plus pericardial bioprosthesis model 6900P mitral. One hundred seventy five (175) patients had isolated mitral replacement (MVR) and 34 patients had double valve replacement (DVR), where the aortic valve was replaced with a Carpentier-Edwards PERIMOUNT pericardial bioprosthesis aortic model. In this study, patients were implanted between 1999 and 2007. Patients were evaluated preoperatively, intraoperatively at discharge, at 1 year, and annually thereafter. Adverse events were captured throughout the postoperative period. Table 2 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 actuarial adverse event rates at 1- and 5-years postoperatively for model 6900P. The adverse event rates were based on two hundred nine (209) patients at seven centers. The cumulative follow-up was 873.18 patient-years with a mean follow-up of 4.2 years (SD = 2.3 years, range = 0 to 8.2 years). Preoperative and operative patient demographics are presented in Tables 4 and 6. Effectiveness results are presented in Tables 8 and 10.

6.2 Potential Adverse Events

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

- Angina
- Cardiac arrhythmias
- Endocarditis
- Heart failure
- Hemolysis
- Hemolytic anemia
- Hemorrhage
- Local and/or systemic infection
- Myocardial infarction
- Prosthesis leaflet entrapment
- Prosthesis nonstructural dysfunction
- Prosthesis pannus
- Prosthesis perivalvular leak
- Prosthesis regurgitation
- Prosthesis structural deterioration
- Prosthesis thrombosis
- Stroke
- Thromboembolism

It is possible that these complications could lead to:

- Reoperation
- Explantation
- Permanent disability
- Death

Other adverse events associated with the use of Carpentier-Edwards PERIMOUNT mitral pericardial bioprostheses model 6900 compiled from the literature and from reports received through the 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, and fracture of the wireform frame.

7.0 Clinical Studies

The safety endpoints captured in the prospective studies were adverse events; blood analyses were used to confirm the absence or presence of certain adverse events. The safety results for model 6900 are provided in Table 1 and for model 6900P in

Table 2. Preoperative patient demographics for model 6900 are provided in Table 3 and for model 6900P in Table 4. Operative patient demographics for model 6900 are provided in Table 5 and for model 6900P in Table 6. Effectiveness endpoints were New York Heart Association (NYHA) functional classification summarized in Table 7 for model 6900 and Table 8 for model 6900P and echocardiographic assessments summarized in Table 9 for model 6900 and Table 10 for model 6900P.

There are no clinical data presently available demonstrating increased resistance of the Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprosthesis model 7300TFX to calcification as compared to other commercially available bioprostheses.

Post-Approval Study

The objective was to evaluate the long-term safety and effectiveness of the Carpentier-Edwards PERIMOUNT Magna Mitral bioprostheses Models 7000/7000TFX and the Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprostheses Models 7200TFX and 7300/7300TFX in patients undergoing mitral valve replacement with or without concomitant procedures requiring cardiopulmonary bypass. This was a prospective, single-arm, multi-center study conducted in the US and outside the US designed to enroll a minimum of 250 subjects implanted with the study valve to achieve 101 mitral valve replacement subjects who complete follow-up for a minimum of 8 years. Clinical assessments of subjects were to be conducted at the preoperative and operative visits, at discharge, and postoperatively at 6 months, 1 year, and annually thereafter for a minimum of 8 years of follow up.

The study population consisted of adult subjects (18 years or older) requiring replacement for a diseased, damaged, or malfunctioning native or prosthetic mitral valve. Subjects that had prior aortic, tricuspid, and/or pulmonary valve surgery which included implant of a valve that remained *in situ* were excluded, along with subjects that required concomitant replacement of a native or prosthetic tricuspid or pulmonic valve, or that had active endocarditis within 3 months of enrolling. Subjects requiring replacement of a native or prosthetic aortic valve with a prosthesis other than a commercially available Carpentier-Edwards PERIMOUNT valve (models 2700, 2700TFX, 2800, 2800TFX, 2900, 3000, 3000TFX, 3300TFX) were also excluded. Various other clinical presentations and histories may have caused exclusion from the study.

Long-term safety was evaluated by comparing observed late linearized rates to objective performance criteria (OPC) described in ISO 5840:2005 (Annex R) for thromboembolism, all hemorrhage, all paravalvular leak (PVL), and endocarditis. Secondary safety endpoints included analyzing early (≤ 30 days postoperatively) and late (> 30 days postoperatively) linearized rates of thromboembolism, valve thrombosis, all hemorrhage (bleeding), major hemorrhage (bleeding), all PVL, major PVL, endocarditis, hemolysis, structural valve deterioration (SVD), non-structural valve dysfunction (NSVD), reoperation, explant, death, and valve-related death. The primary effectiveness endpoint was the proportion of subjects in NYHA Functional Classification I or II at 8 years post implant. The secondary effectiveness endpoint was hemodynamic performance as measured by echocardiography 8 years post implant. Results summarized below includes data from first implant (Sep 2007) to final follow-up (Mar 2024).

During the enrollment period, 19 sites enrolled subjects: 12 in the United States, 2 in Canada, and 5 in Europe. 329 subjects were implanted with either of the 3 valve models (170 with Model 7000TFX, 3 with Model 7200TFX and 156 with Model 7300TFX). Follow-up compliance rates were > 82% across all visits, and follow-up compliance was 85.8% (109/127) at 8 years (**Table 11**).

A total of 127 late primary safety endpoint events were reported in 83 subjects. The 95% upper confidence limits (UCL) for thromboembolism, PVL, and endocarditis endpoints were below twice the EN ISO 5840:2005 Objective Performance Criteria (OPC) rate, but the 95% UCL of rate for bleeding events was above twice the OPC rate (**Table 12**). No late bleeding events were considered related to the study valve. The most common late major bleeding events were gastrointestinal bleeds (41.7%; 20 of 48 events); other events included bleeding related to trauma, soft tissue hematoma, and anemia. These trends do not suggest that the design of the study valve adversely affected the rate of bleeding in the study population.

In the early period, the most common secondary safety endpoint events in the 329 implanted subjects were bleeding (40 events in 39 subjects, 31 of which were major) and death (9 deaths). In the late period, the most common secondary safety endpoint events were bleeding (88 events in 62 subjects, 48 of which were major), death (80 deaths), SVD (27 events in 27 subjects), and thromboembolism (30 events in 25 subjects) (**Table 13**). Kaplan-Meier rates of freedom from event at 8 years were estimated for all-cause mortality (63.8%), study valve-related mortality (96.8%), reintervention (87.8%), explant/valve-in-valve reintervention (90.2%), SVD (83.7%), and reoperation due to SVD (93.6%). Additional freedom from event rates at 8 years were estimated for bleeding (62.5%), thromboembolism (85.0%), NSVD (all: 96.1%; PVL: 97.3%), endocarditis (97.5%), valve thrombosis (99.5%), and hemolysis (100.0%).

Of the 329 implanted subjects, 106 completed a NYHA assessment at 8 years, more than the 101 subjects needed for the primary effectiveness endpoint evaluation. Of these, 87.7% (93/106) had NYHA Class I/II, statistically significantly greater than the pre-specified performance goal of 75% (one-sided p-value = 0.001). For the secondary safety endpoints at 8 years, mean hemodynamic performance results measured by echo examination and reviewed by the echo core lab for peak gradient was 14.57 mmHg, mean gradient (was 5.70 mmHg), EOA (1.90 cm^2), EOA index (1.03 cm^2/m^2), performance index (0.85), cardiac output (6.02 L/min), and cardiac index (3.32 L/min/m^2) (**Table 14**). At 8 years, study valve regurgitation as evaluated by the ECL, yielded no moderate or severe regurgitation, and no paravalvular or indeterminate leak was found in 98.7% of subjects (**Table 15**). Hemodynamic metrics demonstrated improvement from baseline, and these metrics remained clinically stable through 8 years, within expected ranges for most patients across all variables measured.

The Magna Mitral/Magna Mitral Ease valves (models 7000TFX/7200TFX/7300TFX) demonstrated an acceptable safety profile and clinical benefits for patients requiring replacement of their native mitral valve or replacement of a previously implanted mitral valve prosthesis. Study strengths include the design in which study endpoints were defined *a priori*, and both the safety and efficacy outcomes were independently adjudicated by a clinical events committee and an echocardiography core laboratory. Limitations included the study being a single arm study without a control group, which is subject to selection bias. In addition, long term follow-up ran the risk of participants being lost to follow-up, though follow-up compliance for each visit interval through 8 years were above 82%. Additional sensitivity analyses to address missing NYHA data at 8 years demonstrated that the observed rate of NYHA Class I/II at 8 years supported the result from the complete case analysis.

8.0 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 bioprosthesis 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 (Ref. 7).

8.1 Specific Patient Populations

The safety and effectiveness of the Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprosthesis model 7300TFX 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.

9.0 Patient Counseling Information

Careful and continued 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 from bacteremia (e.g., undergoing dental procedures) and should be advised about prophylactic antibiotic therapy. Patients should be encouraged to carry their Implantation Data Card at all times and to inform their healthcare providers that they have a mitral bioprosthetic implant when seeking care.

10.0 How Supplied

10.1 Available Models and Sizes

The Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprosthesis model 7300TFX is available in labeled sizes 25, 27, 29, 31, and 33 mm (see Figure 1 for nominal dimensions).

10.2 Packaging

The Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis is provided sterile and nonpyrogenic packaged in glutaraldehyde, in a plastic jar to which a seal has been applied. Each bioprosthesis is contained in a carton with a temperature indicator displayed through a window on the side panel. The temperature indicator is intended to identify exposure to temperature extremes during transit. Upon receipt of the bioprosthesis, immediately inspect the indicator and refer to the carton label to confirm a "Use" condition. If the "Use" condition is not apparent, do not use the bioprosthesis and contact the local supplier or Edwards Lifesciences representative to make arrangements for return authorization and replacement. Any bioprosthesis returned to Edwards Lifesciences must be shipped in the original packaging in which it was received.

WARNING: The bioprosthesis must be carefully inspected before implantation for evidence of extreme temperature exposure or other damage.

Due to the biological nature of this bioprosthesis and its sensitivity to physical handling and environmental conditions, it cannot be returned, except as noted above.

Note: Products found to have been subjected to freezing or excessive heat later than 3 days following receipt will be considered to have resulted from environmental conditions within the control of the customer, and subject to replacement at customer's expense.

10.3 Storage

The Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis should be stored at 10 °C to 25 °C (50-77 °F). Stock inspection and rotation at regular intervals are recommended to ensure that the bioprostheses are used before the expiration date stamped on the package label.

WARNING: Do not freeze. Always store bioprostheses in a dry, contamination-free area. Any bioprosthesis that has been frozen, or is suspected of having been frozen, should not be used for human implantation.

11.0 Directions for Use

11.1 Physician Training

No special training is required to implant the Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis model 7300TFX. The techniques for implanting this bioprosthesis are similar to those for implanting any stented mitral bioprostheses.

11.2 Accessories

Accessories available for use with the Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis are:

- Tricentrix holder system
- Replica Sizer 1173R (Figure 12)
- Barrel Sizer 1173B (Figure 13)
- Sterilization Tray provided in model SET1173
- Flexible Handle models 1111, 1117, 1173, and 1126 (single use) (Figure 16)

All accessories are supplied non-sterile, except for the Tricentrix holder system that is supplied sterile attached to the sterile bioprosthesis and the handle 1126 that is supplied sterile and is for single use only.

11.2.1 Sizers

Only sizers model 1173B or 1173R may be used with the Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis.

CAUTION: Do not use other manufacturer's valve sizers, or sizers for other Edwards Lifesciences valve prostheses to size the Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis.

Use only the sizers model 1173B or 1173R to determine the appropriate Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis size. Sizers model 1173B and 1173R permit direct observation of their fit within the annulus and are provided for each available Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis size. The barrel of the sizers model 1173B and 1173R indicate the external stent diameter at the base (Figure 1). The lip of the replica sizer 1173R replicates the sewing ring of the bioprosthesis, with its scalloped anterior portion and black markings, to determine the outcomes of specific suture or subvalvular apparatus preservation techniques.

The black marks on the lip replicate the black suture markers on the sewing ring. They delimit the anterior portion of the bioprosthesis sewing ring which should be positioned across the anterior intercommissural portion of the native annulus, in order to straddle the left ventricular outflow tract area. The height and location of the stent posts are marked on the replica sizer 1173R to aid in assessing optimal alignment and seating.

The sizers include preattached handles with increased handle length for improved access in the case of a difficult exposure, a deep thoracic cage or minimally invasive access. The posterior handle attachment to the sizer allows an unobstructed view through the barrel into the ventricle for assessment of

subvalvular structures. The sizers 1173B and 1173R are labeled with the bioprosthesis size.

11.2.2 Tricentrix Holder System and Handles

The holder/handle assembly consists of two (2) components: the Tricentrix holder system that is mounted to the Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis, and a handle (1111, 1117, 1173, or 1126) that is attached to the Tricentrix holder system at the time of surgery (Figure 2).

The following handles (Figure 16) may be used with the Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis:

Model	Shaft Material	Overall Length		Reusable
		inch	cm	
1111	Stainless steel	7.0	17.8	Yes
1117	Nitinol	9.1	23.2	Yes
1126	Stainless steel	11.5	29.2	No
1173	Nitinol	11.3	28.6	Yes

- Handles with a nitinol shaft are more flexible than stainless steel. With each sterilization cycle, they return to their original straight shape for easier attachment to the holder.
- Handle 1173 has been designed to improve access in the case of difficult exposure, a deep thoracic cage, or in minimally invasive procedures.

The Tricentrix holder has short legs and beveled edges to increase suturing space and ease knot tying (Figure 17).

11.3 Accessory Sterilization

The 1126 handle is provided sterile and is intended for single use only. The handles 1111, 1117, and 1173 and the sizers 1173B and 1173R are supplied non-sterile and must be cleaned and sterilized before use. Refer to the Instructions for Use supplied with the reusable accessories for cleaning and sterilization instructions.

11.4 Handling and Preparation Instructions

The bioprosthesis is packaged sterile in a plastic jar with a screw-cap closure and seal. Before opening, carefully examine the jar for evidence of damage (e.g., a cracked jar or lid), leakage, or broken or missing seals. Remove the seal and turn the lid counter-clockwise to open the container. The bioprosthesis and Tricentrix holder system within the container are sterile.

CAUTION: 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.

CAUTION: Bioprostheses from containers found to be damaged, leaking, without adequate glutaraldehyde, or missing intact seals must not be used for human implantation.

CAUTION: It is strongly recommended that the jar of a Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis not be opened unless implantation is certain. This is necessary to reduce the risk of contamination, because it has been established that glutaraldehyde alone is not a 100% effective sterilant against all possible contaminants.

WARNING: No attempt should be made to resterilize a Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis.

WARNING: 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.

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

Verify that the handle, model 1111, 1117, or 1173, has been sterilized according to the instructions provided in the Instructions for Use supplied with the reusable accessories. Attach the handle to the Tricentrix holder system by aligning the handle with the threaded hole in the holder and turning clockwise until a positive resistance is felt. Aligning the handle will ensure a proper and secure attachment. Then remove the whole assembly (i.e., plastic sleeve, clip, the integral holder and bioprosthesis) from the jar. The plastic sleeve is loosely fitted to the clip and may remain in the jar. This will not affect deployment.

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

Grasping the plastic sleeve or clip (Figure 3 or Figure 4) continue the rotation to overcome the resistance until the white holder post reaches the unlock position (Figure 5 and Figure 6). Apply the required push force on the handle until the white holder post slides across the leaflets and snaps into its fully deployed position (Figure 7). An audible click may be heard as the deployed position is reached.

CAUTION: If an adequate push force is not applied to the handle when deploying the Tricentrix holder system, the tenting system will not be secured and will not be able to minimize the potential for suture entrapment. Always check for proper deployment. There should be no more space between the blue adapter and the grey holder. The handle/post assembly should no longer be able to slide.

The white holder post should protrude through the leaflets while the three (3) commissures should deflect slightly towards the center of the bioprosthesis. The leaflets will temporarily be wrinkled by the deployed white holder post. When the holder is removed following implantation, the leaflets will return to their normal position.

After deployment, remove the sleeve (if attached) by holding the handle and pulling the sleeve off the clip (Figure 8). Remove the clip by sliding it off the holder in a sideways direction (Figure 9). Both sleeve and clip should be discarded. Once the handle has been attached, it should not be removed from the holder until the bioprosthesis is seated to the annulus.

11.4.1 Rinse Procedure

Within the sterile operative field, prepare two rinse basins, each containing no less than 500 ml of sterile, physiological saline solution. Place the deployed bioprosthesis in the saline solution and make sure that it completely covers the bioprosthesis and holder. Do not rinse with the sleeve and clip attached. With the bioprosthesis and holder submerged, slowly agitate the basin or use the attached handle to gently swirl the bioprosthesis back and forth for a minimum of 1 minute in each of the two previously prepared rinse basins. The bioprosthesis should remain in the second rinse basin until ready for implantation.

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

CAUTION: Do not allow the leaflet 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 leaflet tissue during rinsing. Inspect the bioprosthesis and remove the serial number tag just prior to implantation. Exercise care to avoid cutting or tearing the sewing ring cloth during removal of the serial number tag.

11.5 Device Implantation

Because of the complexity and variation in the surgical procedure of cardiac valve replacement, the choice of surgical technique is left to the discretion of the individual surgeon. In general, the standard implantation technique includes: 1. Proper sizing; 2. Proper seating of the prosthesis; 3. Tying sutures with the holder in place to minimize the potential for suture looping or chordal entrapment; 4. Examination of the bioprosthetic leaflets for distortion or leak during tying.

Proper bioprosthesis size selection is an important part of mitral valve replacement.

Verify that the sizers 1173B and 1173R have been sterilized according to the recommended instructions provided with the reusable accessories.

CAUTION: Examine sizers and handles for signs of wear, such as dullness, cracking, or crazing. Replace sizer or handle if any deterioration is observed.

WARNING: Fragments of the sizers / handles cannot be located by means of an external imaging device.

CAUTION: Adequate removal of calcium deposits from the patient's annulus must be performed before implantation to avoid damage to the delicate bioprosthesis leaflet tissue as a result of contact with calcium deposits.

Insert the sizer into the mitral annulus. The barrel of the sizer should always fit comfortably in the annulus.

CAUTION: Use only sizers 1173B or 1173R during the selection of the Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis size; other sizers may result in improper valve selection (see 11.2 Accessories). Like other mitral bioprostheses, the Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis is usually implanted using pledgeted mattress sutures. It is recommended to size the annulus after the sutures have been placed, as sutures may decrease the size of the bioprosthesis that can be implanted.

11.5.1 Sizing for Implantation

Sizing with barrel sizer 1173B: To size with barrel sizer 1173B, pass the barrel portion of the sizer through the mitral annulus ensuring the barrel portion is directly in the plane of the mitral annulus (Figure 15).

Sizing with replica sizer 1173R: To size with replica sizer 1173R, pass the barrel portion of the sizer through the mitral annulus so that the lip of the sizer, which simulates the sewing ring portion of the bioprosthesis, rests on the superior aspect of the annulus (Figure 14).

Some techniques such as use of pledgets, leaflet reefing, or mitral subvalvular apparatus preservation may further reduce the size of the mitral annulus which can result in the need for a smaller bioprosthesis to be implanted (Ref. 8). When using these techniques, it is recommended to re-size the annulus to avoid oversizing of the bioprosthesis. The consistent performance of the Carpentier-Edwards PERIMOUNT mitral bioprostheses makes oversizing unnecessary to achieve the desired hemodynamic performance in most patients (Table 9 and 10).

Due to the elastic nature of a chord, it may be extended by the Tricentrix holder system during implantation but retract back around the post once the holder is removed, entrapping leaflets and impairing function. Sizers 1173B and 1173R are made of a transparent material to allow visualization of the subvalvular apparatus during sizing. Make sure no chord will be in the way of the struts.

CAUTION: Exercise special care when using subvalvular apparatus preservation techniques to avoid chordae entrapment by a strut.

WARNING: Avoid oversizing the bioprosthesis. Oversizing may cause bioprosthesis damage or localized mechanical stresses, which may in turn injure the heart or result in leaflet tissue failure, stent distortion and regurgitation.

CAUTION: Because of the intense temperature and lighting conditions in the operating field, the bioprosthesis should be irrigated frequently (every 1 to 2 minutes is recommended) on both sides with sterile physiological saline to keep the valve moist during the implant procedure.

11.5.2 Proper Orientation of the Bioprosthesis

CAUTION: The wireform frame of the Carpentier-Edwards PERIMOUNT Magna Mitral Ease bioprosthesis is symmetrical, and the three commissure supports (struts) are equally spaced. However, the sewing ring is designed for a specific orientation of the bioprosthesis. The scalloped part of the sewing ring, between the two silicone protrusions, should be placed across the intercommissural anterior portion of the annulus and straddle the left ventricular outflow tract.

The contrasting suture markers in the sewing ring are intended to aid in proper orientation and denote a typical intercommissural distance. However, this distance may vary for each individual patient. On the left side, two close black sutures indicate where the first stitch should be placed and correspond to the anterior commissure. On the right side, only one black suture indicates the approximate location of the posterior commissure. Using these orientation aids, the third post should naturally fall in place in or around the middle of the posterior leaflet location.

CAUTION: Special care must be exercised to avoid placing a strut in front of the left ventricular outflow tract, as it may impair the long-term hemodynamic performance.

A black suture guide line circles the sewing ring. When placing sutures through the sewing ring, sliding drag forces are reduced when sutures are placed straight through the sewing ring and in the region from the suture guide line to the outer portion of the sewing ring. Irrigation with saline can further reduce suture drag forces.

Firm tension must be maintained on the sutures as the bioprosthesis is lowered into the annulus; this minimizes the potential for formation of suture loops that might entrap a leaflet. This, when combined with the fully retracted stent posts when the Tricentrix holder system is in place, helps guide the sutures into their correct position behind the struts and onto the sewing ring.

Remove the handle prior to tying the sutures. The handle and blue adapter must be removed as an assembly. Maintain the bioprosthesis placement in the annulus by gently placing forceps or gloved hands onto the holder and cutting the green thread on the blue adapter (Figure 10). Remove the blue adapter and handle assembly as one unit.

CAUTION: Exercise care when lowering and seating the bioprosthesis into the annulus. Avoid looping or catching a suture around the open cages, free struts or commissure support of the bioprosthesis, which would interfere with proper valvular function. To minimize the potential for suture looping, it is essential to avoid excessive lateral forces

to the Tricentrix holder and leave the deployed holder in place until all knots are tied.

However, if leaving the holder in place obstructs the surgeon's view, all the sutures adjacent to each of the three frame struts must be tied down before cutting the three green holder attachment threads to remove the holder.

CAUTION: If the deployed holder attachment threads are cut before these adjacent sutures are tied down, the holder will no longer minimize the potential for suture looping around the frame struts.

Special attention must be given to avoid tying the sutures on top of the corners of the holder's grey legs. Before tying each suture, examine the leaflets while holding the two strands of the suture under tension. Distortion or movement of the leaflets during this maneuver suggests that the suture is looped around a strut. At no point before or after holder removal should tension on the sutures be released as this may facilitate formation of loops in the sutures and possible entrapment. It is recommended to place a surgical mirror through the leaflets after the holder removal in order to examine each strut and proper suture placement.

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 (Ref. 8).

The Tricentrix holder system is removed as a unit at the completion of the suturing procedure as follows (Figure 11):

Step	Procedure
1	Cut each of the three (3) exposed green sutures using a scalpel or scissor placed only in the cutting channel. Never attempt to cut a suture below a partially separated holder as a part of the attaching suture may fall in the ventricle. 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 Tricentrix holder system from the bioprosthesis as a unit, along with attaching sutures, using sterile gloved hands or protected forceps.
3	Following surgery, remove the holder and discard.

11.6 Return of Explanted Bioprostheses

Edwards Lifesciences is interested in obtaining all recovered clinical specimens of Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprostheses model 7300TFX for analysis. A written report summarizing our findings will be provided to the physician upon completion of our evaluation. Please contact your local representative for return of recovered bioprostheses. The explanted bioprostheses should be placed into a suitable histological fixative such as 10% formalin or 2% glutaraldehyde immediately after excision and returned to the company. Refrigeration is not necessary under these circumstances.

12.0 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 bioprosthesis serial number is listed on the bioprosthesis 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 the Edwards 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 bioprosthesis is discarded or a previous Edwards Lifesciences device is replaced, report this information to the Edwards Implant Patient Registry.

12.2 Patient Manual

Patient information materials may be obtained from Edwards or your local representative.

13.0 Safety in the Magnetic Resonance (MR) Environment

MR Conditional

Non-clinical testing has demonstrated that the Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprosthesis model 7300TFX is MR Conditional. A patient with the valve can be scanned safely, in an MR system meeting the following conditions:

- Static magnetic field of 3 tesla or less.
- Spatial gradient field of less than 3000 gauss/cm.
- Maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg in the normal operating mode.

Under the scan conditions defined above the Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprosthesis, model 7300TFX is expected to produce a maximum temperature rise of 2.3 °C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately as far as 36 mm from the Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprosthesis when imaged with a gradient echo pulse sequence and approximately as far as 11.5 mm from the device when imaged with a spin echo pulse sequence and a 3 T MRI system. The lumen is partially to fully obscured under these conditions.

Prices subject to change without notice.

14.0 References

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Table 1: Observed Adverse Event Rates for MVR and DVR (Model 6900)

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 = 287)	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]
Valve-related events							
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 events.

Table 2: Observed Adverse Event Rates (Model 6900P)

All patients analyzed: N = 209 Cumulative follow-up: 873.18 total pt-yrs.

Complication	Early Events		Late Events[1]		Freedom from Event (%) [95% CI][2]	
	n[3]	%	n	%/pt-yr	1 year	5 years
Mortality (all)	3	1.4	45	5.3	93.2 [88.8, 95.9]	74.4 [66.9, 80.5]
Valve-related events						
Mortality (valve-related)	1	0.5	12	1.4	98.5 [95.5, 99.5]	92.0 [86.2, 95.5]
Explants	1	0.5	8	0.9	97.5 [94.0, 98.9]	96.5 [92.2, 98.5]
Reoperations	0	0.0	0	0.0	100.0 [100, 100]	100.0 [100, 100]
Bleeding Events	5	2.4	13	1.5	96.1 [92.3, 98.0]	91.9 [86.5, 95.2]
Endocarditis	1	0.5	3	0.4	99.5 [96.6, 99.9]	97.1 [92.1, 98.9]
Nonstructural dysfunction	0	0.0	1	0.1	99.5 [96.4, 99.9]	99.5 [96.4, 99.9]
Perivalvular leak (all)	1	0.5	2	0.2	99.5 [96.7, 99.9]	98.4 [95.2, 99.5]
Structural valve deterioration	0	0.0	2	0.2	100.0 [100, 100]	99.0 [93.2, 99.9]
Thromboembolism	4	1.9	12	1.4	97.0 [93.5, 98.7]	91.3 [85.8, 94.7]
Thrombosis	0	0.0	0	0.0	100.0 [100, 100]	100.0 [100, 100]

Notes:

1. Late event rates were calculated as linearized rates (%/pt-yr) based on 856.24 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 events.

Table 3: Preoperative Patient Demographics (Model 6900)

Variable	Category	Study Characteristics (N = 363; 1100 total pt-yrs.)	
		n	% (n/N)[1]
Age at implant (N = 363)	Mean ± SD	66.1 ± 10.7	
Gender	Female/Male	212/151	58.4%/41.6%

Variable	Category	Study Characteristics (N = 363; 1100 total pt-yrs.)	
		n	% (n/N)[1]
Diagnosis/Etiology	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 4: Preoperative Patient Demographics (Model 6900P)

Variable	Category	Study Characteristics (N = 209; 873.18 total pt-yrs.)	
		n	% (n/N)[1]
Age at implant (N = 209)	Mean ± SD	71.4 ± 9.4	
Gender	Female/Male	138/71	66.0%/34.0%
Diagnosis/Etiology	Mixed Disease	48	23.0%
	Regurgitation	121	57.9%
	Stenosis	32	15.3%
	Valve Dysfunction	8	3.8%

Note:

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

Table 5: Operative Patient Demographics (Model 6900)

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%

Variable	Category	Study Characteristics (N = 363; 1100 total pt-yrs.)	
		n	% (n/N)[1]
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
4. Permanent or temporary
5. CAD = Coronary Artery Disease
6. MI = Myocardial Infarction

Table 6: Operative Patient Demographics (Model 6900P)

Variable	Category	Study Characteristics (N = 209; 873.18 total pt-yrs.)	
		n	% (n/N)[1]
Etiology[2]	Calcified	38	18.2%
	Congenital	1	0.5%
	Degenerative	105	50.2%
	Endocarditis Remote	10	4.8%
	Ischemic	12	5.7%
	Rheumatic	64	30.6%
	Other	36	17.2%
Concomitant Procedures[2]	None	91	43.5%
	Aortic Valve/Annulus Repair	3	1.4%
	CABG[3]	58	27.8%
	Permanent Pacemaker	1	0.5%
	Tricuspid Valve/Annulus Repair	21	10.0%
	Other	78	37.3%
Pre-existing Conditions[2]	None	17	8.1%
	Arrhythmias	95	45.5%
	CAD[4]	85	40.7%
	Cardiomyopathy	13	6.2%
	Congestive Heart Failure	66	31.6%
	Endocarditis	14	6.7%
	Myocardial Infarction	21	10.0%
	Peripheral Vascular Disease	9	4.3%
	Pulmonary Hypertension	66	31.6%
	Rheumatic Fever	16	7.7%
	Systemic Hypertension	49	23.4%
	TIA[5]/CVA[6]	24	11.5%
	Other	35	16.7%
Valve Size (mm)	25	28	13.4%
	27	37	17.7%
	29	84	40.2%
	31	43	20.6%
	33	17	8.1%

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
4. CAD = Coronary Artery Disease
5. TIA = Transient Ischemic Attack
6. CVA = Cerebral Vascular Accident

Table 7: Effectiveness Outcomes, Functional NYHA (Model 6900)

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 8: Effectiveness Outcomes, Functional NYHA (Model 6900P)

NYHA Functional Class	Preoperative Assessment		Postoperative Assessments			
			1 Year		5 Year	
	n/N[1]	%	n/N	%	n/N	%
I	6/209	2.9	86/187	46.0	30/96	31.3
II	27/209	12.9	68/187	36.4	33/96	34.4
III	121/209	57.9	8/187	4.3	6/96	6.3
IV	55/209	26.3	1/187	0.5	0/96	0.0
Not Available	0/209	0.0	24/187	12.8	27/96	28.1

Note:

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

Table 9: Effective Outcomes, Hemodynamic Results[1] (Model 6900)

Hemodynamic Parameter	Results By Valve Size				
	25 mm	27 mm	29 mm	31 mm	33 mm
Discharge/Early Post-Implant (n = 130, 109 MVR[2] and 21 DVR[3])					
Mean gradient[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%)
3 to 6 Month Post-Implant Interval (n = 49, 42 MVR[2] and 7 DVR[3])					
Mean gradient[4]	n = 5	n = 19	n = 15	n = 5	n = 2

Hemodynamic Parameter	Results By Valve Size				
	25 mm	**27 mm**	**29 mm**	**31 mm**	**33 mm**
• 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%)
1 to 2 Year Post-Implant Interval (n = 131, 114 MVR[2] and 17 DVR[3])					
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%)
5 Year Post-Implant Interval (n = 11, 9 MVR[2] and 2 DVR[3])					
Mean gradient[4]	n = 0	n = 6	n = 5	n = 0	n = 0
• mean ± sd	N/A	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%)	0/6 (0%)	0/5 (0%)	0/0 (0%)	0/0 (0%)
Not available	0/0 (0%)	0/6 (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 mmHg
5. EOA: Effective Orifice Area, cm^2
6. Regurgitation = none, 0; mild, 1+; moderate, 2+; moderate/severe, 3+; severe, 4+

Table 10: Effectiveness Outcomes, Hemodynamic Results (Model 6900P)[1]

Hemodynamic Parameter	Results By Valve Size				
	25 mm	27 mm	29 mm	31 mm	33 mm
Discharge/Early Post-Implant					
Mean gradient[2]	n = 24	n = 35	n = 83	n = 42	n = 16
• mean ± sd	6.4 ± 1.87	4.4 ± 1.52	3.4 ± 1.47	3.3 ± 1.20	4.0 ± 1.38
• min, max	3, 10	1.96, 8	1.4, 9	1, 7	1.5, 6.91
EOA[3]	n = 8	n = 27	n = 77	n = 41	n = 16
• mean ± sd	2.7 ± 0.87	2.8 ± 0.58	2.9 ± 0.93	2.5 ± 0.67	2.4 ± 0.52
• min, max	1.46, 4.4	1.5, 3.9	1.58, 6	1.32, 4.2	1.55, 3.31
Regurgitation[4]	n = 27	n = 37	n = 83	n = 43	n = 17
Trivial/None	19/27 (70%)	29/37 (78%)	76/83 (92%)	39/43 (91%)	15/17 (88%)
1+ Mild	6/27 (22%)	7/37 (19%)	7/83 (8%)	4/43 (9%)	1/17 (6%)
2+ Moderate	1/27 (4%)	1/37 (3%)	0/83 (0%)	0/43 (0%)	0/17 (0%)
3+ Moderate/Severe	0/27 (0%)	0/37 (0%)	0/83 (0%)	0/43 (0%)	1/17 (6%)
4+ Severe	0/27 (0%)	0/37 (0%)	0/83 (0%)	0/43 (0%)	0/17 (0%)
Not available	1/27 (4%)	0/37 (0%)	0/83 (0%)	0/43 (0%)	0/17 (0%)
3 to 6 Month Post-Implant Interval					
Mean gradient[2]	n = 0	n = 4	n = 3	n = 2	n = 0
• mean ± sd	0 ± 0	4.4 ± 2.25	2.3 ± 0.89	6.6 ± 2.05	0 ± 0
• min, max	0, 0	2.5, 7.5	1.3, 3	5.1, 8	0, 0
EOA[3]	n = 0	n = 3	n = 3	n = 1	n = 1
• mean ± sd	0 ± 0	2.4 ± 0.74	3.2 ± 0.88	2.5 ± 0.00	1.2 ± 0.00
• min, max	0, 0	1.6, 3	2.3, 4.05	2.47, 2.47	1.22, 1.22
Regurgitation[4]	n = 0	n = 5	n = 3	n = 2	n = 2
Trivial/None	0	3/5 (60%)	2/3 (67%)	2/2 (100%)	2/2 (100%)
1+ Mild	0	1/5 (20%)	1/3 (33%)	0/2 (0%)	0/2 (0%)
2+ Moderate	0	1/5 (20%)	0/3 (0%)	0/2 (0%)	0/2 (0%)
3+ Moderate/Severe	0	0/5 (0%)	0/3 (0%)	0/2 (0%)	0/2 (0%)
4+ Severe	0	0/5 (0%)	0/3 (0%)	0/2 (0%)	0/2 (0%)
Not available	0	0/5 (0%)	0/3 (0%)	0/2 (0%)	0/2 (0%)
1 Year Post-Implant Interval					
Mean gradient[2]	n = 16	n = 27	n = 63	n = 34	n = 15
• mean ± sd	5.9 ± 2.36	4.0 ± 1.45	3.0 ± 1.61	3.3 ± 1.26	3.4 ± 1.25
• min, max	3, 12	2, 7	1, 12	1.5, 7	1.9, 6.3
EOA[3]	n = 3	n = 21	n = 59	n = 32	n = 15
• mean ± sd	2.3 ± 0.16	2.4 ± 0.76	2.6 ± 0.74	2.5 ± 0.67	2.3 ± 0.83

Hemodynamic Parameter	Results By Valve Size				
	25 mm	27 mm	29 mm	31 mm	33 mm
• min, max	2.09, 2.4	1.27, 4.76	1.5, 5.7	1.5, 4	1.2, 3.8
Regurgitation[4]	n = 20	n = 28	n = 65	n = 34	n = 16
Trivial/None	17/20 (85%)	24/28 (86%)	53/65 (82%)	29/34 (85%)	13/16 (81%)
1+ Mild	3/20 (15%)	3/28 (11%)	6/65 (9%)	3/34 (9%)	3/16 (19%)
2+ Moderate	0/20 (0%)	0/28 (0%)	3/65 (5%)	2/34 (6%)	0/16 (0%)
3+ Moderate/Severe	0/20 (0%)	0/28 (0%)	1/65 (2%)	0/34 (0%)	0/16 (0%)
4+ Severe	0/20 (0%)	0/28 (0%)	0/65 (0%)	0/34 (0%)	0/16 (0%)
Not available	0/20 (0%)	1/28 (4%)	2/65 (3%)	0/34 (0%)	0/16 (0%)

Notes:

1. Hemodynamic evaluations were performed using transthoracic echocardiography (TTE) and in some cases, transesophageal echocardiography (TEE).
2. Mean gradient in mmHg
3. EOA: Effective Orifice Area, cm^2
4. Regurgitation = Trivial/none, 0; mild, 1+; moderate, 2+; moderate/severe, 3+; severe, 4+

Table 11: Subject Accountability, Implanted Cohort (N = 329)

	Discharge	6 Month	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
Patients with known visit accountability[a]	100% (329/329)	100% (329/329)	100% (329/329)	100% (329/329)	100% (329/329)	100% (329/329)	100% (329/329)	100% (329/329)	100% (329/329)	100% (329/329)
On study at follow-up visit[b]	320	295	274	250	228	208	191	170	146	127
Visit Completed	313	274	254	219	204	184	158	145	122	109
Missed visit	7	21	20	31	24	24	33	25	24	18
Compliance	98% (313/320)	93% (274/295)	93% (254/274)	88% (219/250)	89% (204/228)	88% (184/208)	83% (158/191)	85% (145/170)	84% (122/146)	86% (109/127)
Discontinued prior to follow-up visit[c]	9	34	55	79	101	121	138	159	183	202
Death[d]	7	23	28	37	42	51	60	72	80	88
Reoperation/ Explant[e]	2	3	3	6	7	7	8	11	13	17
Patient withdrew consent	0	5	15	20	30	35	38	40	44	45
Lost to follow up	0	0	1	3	4	8	11	16	25	30
Exit with other reason[f]	0	3	8	13	18	20	21	20	21	22

[a] The patients with known accountability are calculated as follows: (Numbers with follow-up visits + those with missed visit + those who have exited the study before the upper limit of the visit window)/the total population.

[b] On study at follow-up visit = Visit Completed + Missed Visit

[c] This includes all patients who exited the study prior to the end of the follow-up visit window and who have not had the visit.

[d] One death occurred after the 8-year visit but while the subject was still on study.

[e] This category includes all reinterventions. Beyond the 17 reinterventions included here, 8 additional reinterventions occurred; 5 were in subjects who died and thus are only counted under "Death," and 3 were in subjects who completed an 8-year follow-up visit and thus are only counted as "Visit completed." Of the 25 events reported as reinterventions, 2 were surgical interventions not on the study valve.

[f] Other reasons for exiting included sites failing to contact patient, and patient unable or unwilling to come to follow-up visits.

Compliance = Visit Completed/ (Visit Completed + Missed Visit)

Table 12: Summary of Late Primary Safety Endpoints, Implanted Cohort (N = 329)

		All Events	
Event	**n, m (m/LPY) LPY = 1515.9**	**95% UCL**	**2X OPC Rate**

Thromboembolism	25, 30 (2.0%)	2.6%	5.0%
All Bleeding Events	62, 88 (5.8%)	6.9%	2.8%
All Paravalvular Leak	4, 4 (0.3%)	0.6%	2.4%
Endocarditis	5, 5 (0.3%)	0.6%	2.4%
Total Events	83, 127 (8.4%)	9.7%	---

Note:

1. n is the number of subjects with an event; m is the number of events; LPY: Late patient-years (pt-yr); UCL: Upper confidence limit Late linearized rates reported as m/LPY.

Table 13: Summary of Secondary Safety Endpoints, Implanted Cohort (N = 329)

	Early Events	**Late Events**
Endpoint	**n, m (m/N) N = 329**	**n, m (m/LPY) LPY = 1515.9**
Thromboembolism	7, 7 (2.1%)	25, 30 (2.0%)
Valve Thrombosis	0, 0 (0.0%)	1, 1 (0.1%)
All Bleeding Events	39, 40 (12.2%)	62, 88 (5.8%)
Major Bleeding	30, 31 (9.4%)	35, 48 (3.2%)
Endocarditis	0, 0 (0.0%)	5, 5 (0.3%)
Hemolysis	0, 0 (0.0%)	0, 0 (0.0%)
Structural Valve Deterioration	0, 0 (0.0%)	27, 27 (1.8%)
Non-Structural Valve Dysfunction	5, 5 (1.5%)	6, 6 (0.4%)
Paravalvular Leak	5, 5 (1.5%)	4, 4 (0.3%)
Major PVL	5, 5 (1.5%)	2, 2 (0.1%)
Reoperation [a]	3, 3 (0.9%)	3, 3 (0.2%)
Explant [a]	3, 3 (0.9%)	16, 16 (1.1%)
Death	9, 9 (2.7%)	80, 80 (5.3%)
Valve-related Death	1, 1 (0.3%)	4, 4 (0.3%)

Note:

1. [a] Of the 3 late events reported as reoperations, 2 were non-valve-related interventions, and 1 was a valve-in-valve reintervention. Of the 16 late events reported as explants, 10 were surgical explants, and 6 were valve-in-valve reinterventions. Therefore, the total number of valve-in-valve reinterventions is 7.

Table 14: Hemodynamic Performance at Baseline and 8 Years

Parameter	**Baseline** **N: Mean ± SD** **Median (Q1, Q3)** **[Min, Max]**	**8 Years** **N: Mean ± SD** **Median (Q1, Q3)** **[Min, Max]**
Peak Gradient (mmHg)	176: 18.56 ± 9.63 18.00 (11.00, 24.00) [1.20, 56.00]	73: 14.57 ± 6.62 13.00 (10.00, 17.00) [5.70, 40.00]
Mean Gradient (mmHg)	175: 8.03 ± 5.42 6.80 (3.70, 11.50) [1.10, 29.00]	71: 5.70 ± 2.85 5.10 (3.50, 7.00) [2.30, 15.00]
EOA (cm^2)	110: 1.39 ± 0.93 1.14 (0.78, 1.82) [0.33, 5.67]	60: 1.90 ± 0.67 1.82 (1.51, 2.07) [0.93, 5.00]
EOA Index (cm^2/m^2)	110: 0.73 ± 0.48 0.60 (0.42, 0.85) [0.20, 2.71]	60: 1.03 ± 0.38 0.99 (0.78, 1.19) [0.48, 2.50]
Performance Index	110: 0.63 ± 0.44 0.48 (0.37, 0.77) [0.17, 2.49]	60: 0.85 ± 0.31 0.77 (0.67, 1.00) [0.40, 1.99]
Cardiac Output (L/min)	138: 4.70 ± 1.67 4.40 (3.60, 5.40) [1.80, 10.10]	60: 6.02 ± 1.52 5.80 (4.75, 7.00) [2.80, 10.00]

Cardiac Index (L/min/m^2)	98: 2.50 ± 0.86 2.38 (1.90, 2.90) [1.10, 4.80]	55: 3.32 ± 0.91 3.20 (2.70, 4.10) [1.40, 5.50]

Table 15: Mitral Valve Regurgitation, Implanted Cohort (N =329)

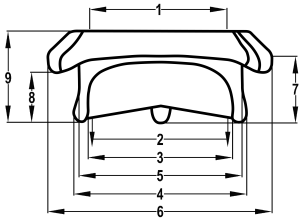
Visit	Severity	Paravalvular Leak % (n/N)	Central Leak % (n/N)	Indeterminate Leak[a] % (n/N)
Preoperative	0 None	99.6 (275 /276)	5.4 (15 /278)	99.6 (274 /275)
	+1 Trivial/Trace	0.0 (0 /276)	5.0 (14 /278)	0.0 (0 /275)
	+2 Mild	0.0 (0 /276)	25.2 (70 /278)	0.0 (0 /275)
	+3 Moderate	0.0 (0 /276)	28.8 (80 /278)	0.4 (1 /275)
	+4 Severe	0.4 (1 /276)	35.6 (99 /278)	0.0 (0 /275)
8 Years	0 None	98.7 (76 /77)	54.5 (42 /77)	98.7 (76 /77)
	+1 Trivial/Trace	1.3 (1 /77)	23.4 (18 /77)	0.0 (0 /77)
	+2 Mild	0.0 (0 /77)	22.1 (17 /77)	1.3 (1 /77)
	+3 Moderate	0.0 (0 /77)	0.0 (0 /77)	0.0 (0 /77)
	+4 Severe	0.0 (0 /77)	0.0 (0 /77)	0.0 (0 /77)

N is the number of subjects with available data.

[a] If a determination of leak location (paravalvular or central) could not be made, the regurgitation severity was recorded under 'Indeterminate.'

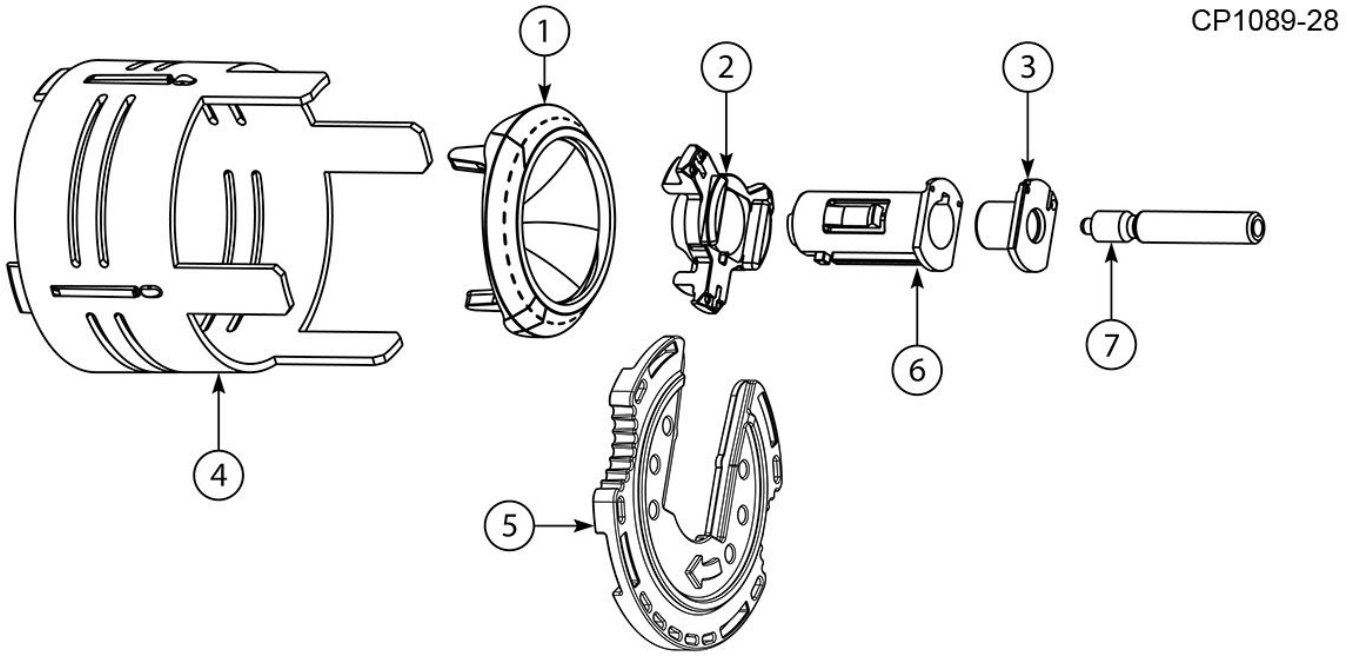
Figures

Carpentier-Edwards PERIMOUNT Magna Mitral Ease Pericardial Bioprosthesis, Model 7300TFX



Size	25 mm	27 mm	29 mm	31 mm	33 mm
1. Inflow Orifice Diameter (mm)	23.0	25.0	27.0	29.0	29.0
2. Effective Orifice Diameter (mm)	18.0	20.0	22.0	22.5	22.5
3. Stent Diameter (Wireform, mm)	25	27	29	31	31
4. External Stent Post Diameter (Tip, mm)	29	31	34	35	35
5. Valve Housing External Diameter (mm)	27.5	29.5	31.5	33.5	33.5
6. External Sewing Ring Diameter (mm)	36.0	37.5	40.0	42.0	44.5
7. Effective Profile Posterior (mm)	10	10.5	11	11.5	11.5
8. Effective Profile Anterior (mm)	7	7.5	8	8.5	8.5
9. Total Profile Height (mm)	15	16	17	18	18

Figure 1: Nominal Dimensions (mm)



Tricentrix holder system:

- Holder
- Adapter
- Post
- Clip
- Sleeve

1 Valve
2 Holder
3 Adapter
4 Sleeve
5 Clip
6 Post
7 Handle

Figure 2

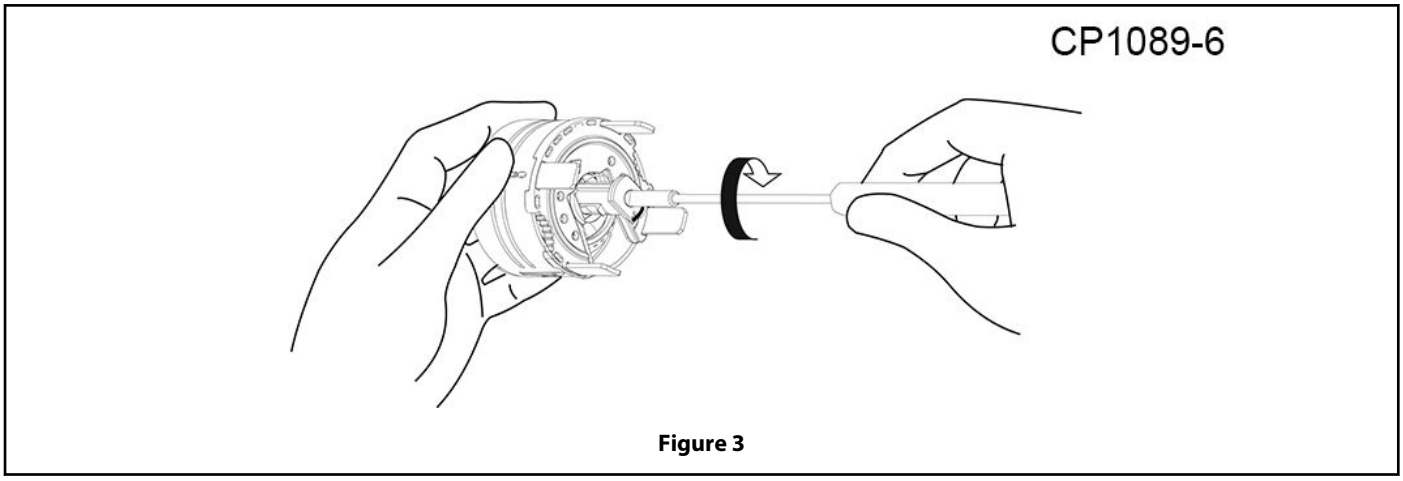


Figure 3

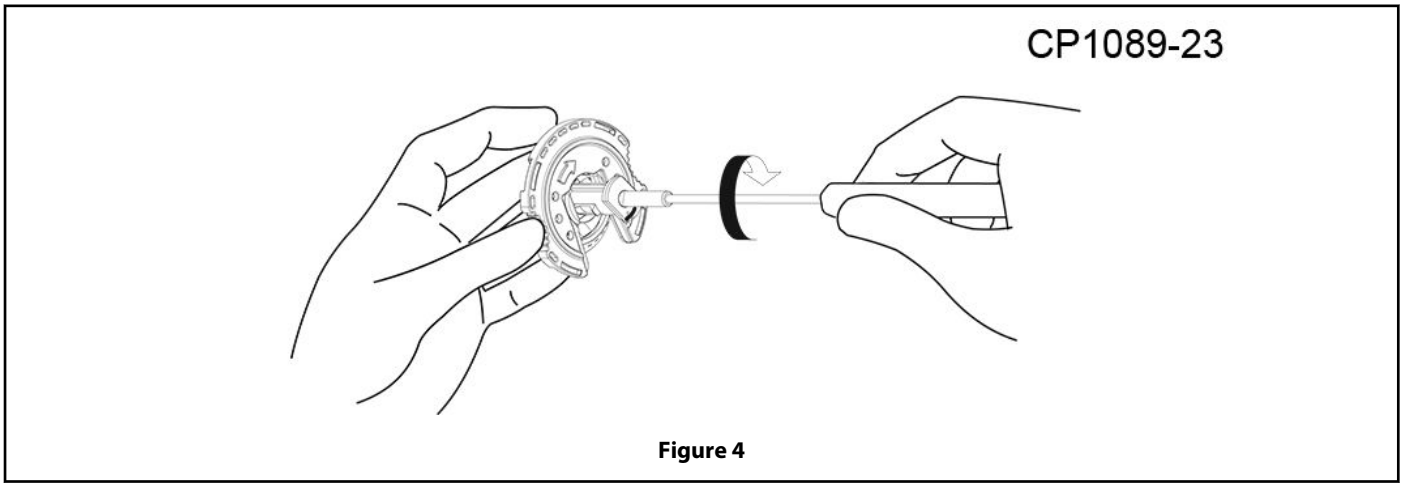
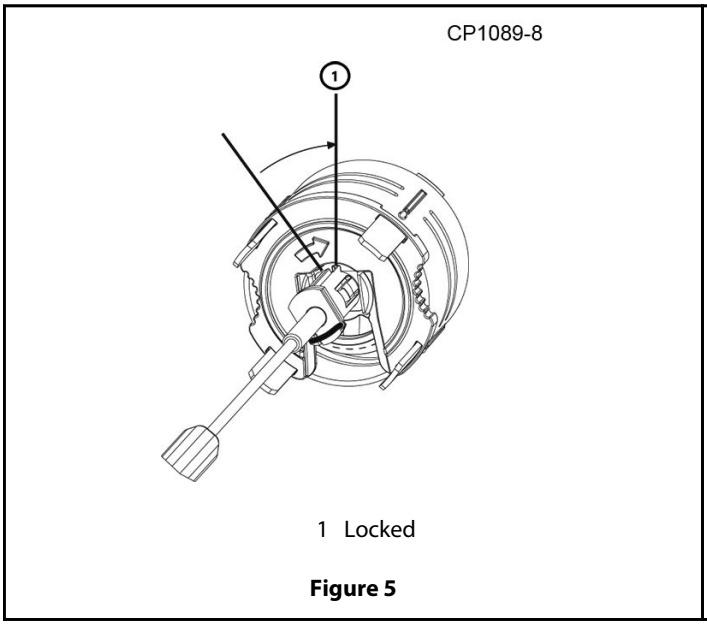
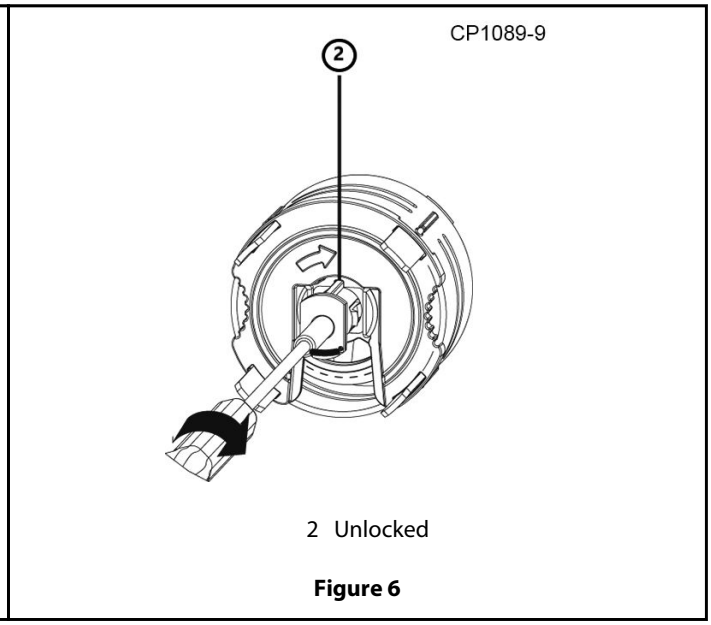


Figure 4



1 Locked

Figure 5



2 Unlocked

Figure 6

CP1089-24

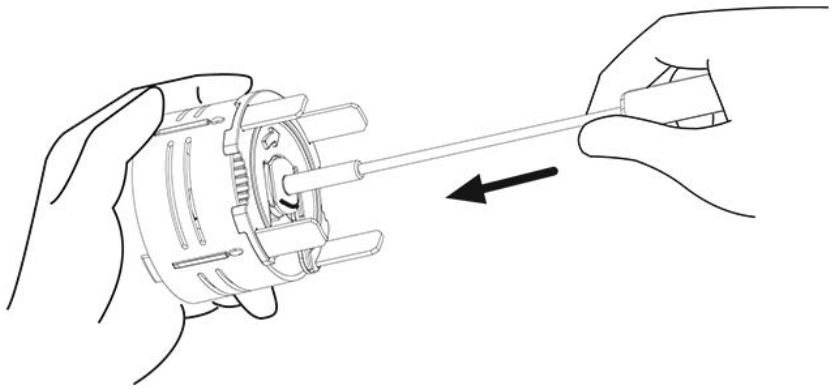


Figure 7

CP1089-25

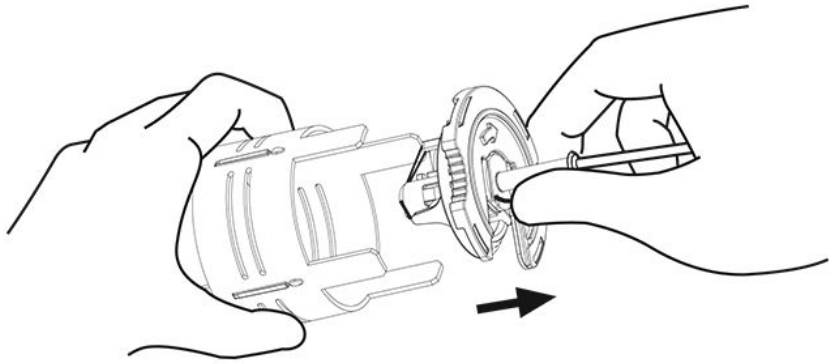


Figure 8

CP1089-26

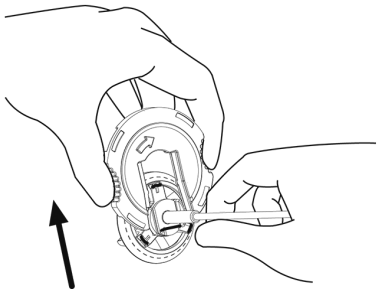
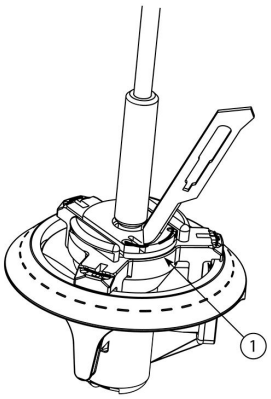


Figure 9

CP1089-27



1 Adapter

Figure 10

CP1089-14

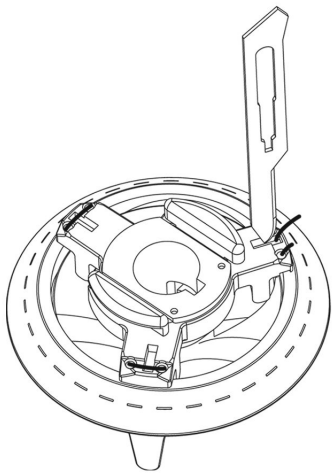
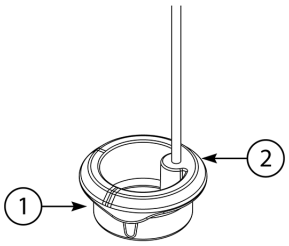


Figure 11

CP1089-15



1 Barrel
2 Lip

Figure 12: Replica Sizer 1173R

CP1089-16

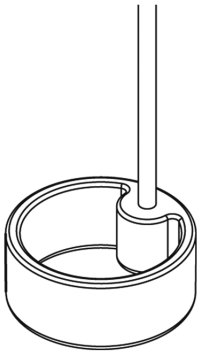


Figure 13: Barrel Sizer 1173B

CP1083-41

Figure 14: Annular Seating with Replica Sizer

CP1089-17

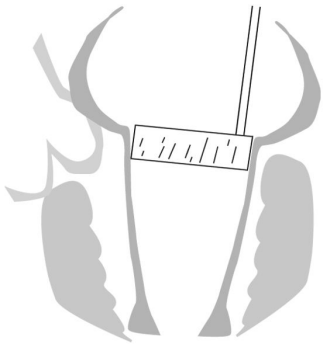
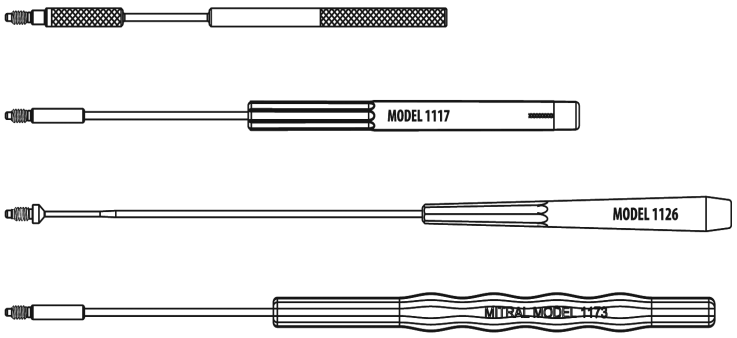


Figure 15: Annular Seating with Barrel Sizer

CP1089-29



Model	Length	
	inch	cm
1111	7.0	17.8
1117	9.1	23.2
1126	11.5	29.2
1173	11.3	28.6

Figure 16

CP1089-2a

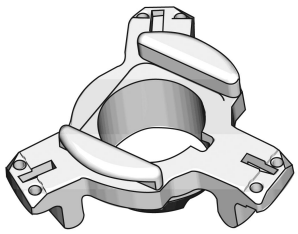


Figure 17

CP1089-19

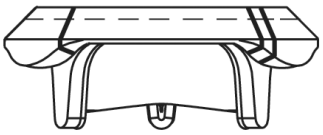


Figure 18

2025-08
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