Carpentier-Edwards PERIMOUNT
Magna Ease Pericardial Bioprosthesis Model 3300TFX Aortic

A PERI valve

For single use only

1.0 Device Description

The Edwards Carpentier-Edwards PERIMOUNT Magna Ease aortic pericardial bioprosthesis model 3300TFX (also referred to as the Magna Ease aortic bioprosthesis) is a trileaflet bioprosthesis comprised of bovine pericardium that has been preserved in a buffered glutaraldehyde solution and mounted on a flexible frame. The bioprosthesis is treated according to the Edwards ThermaFix process, which involves heat treatment of the tissue in glutaraldehyde and uses ethanol and polysorbate-80 (a surfactant). The bioprosthesis is packaged and terminally sterilized in glutaraldehyde. Glutaraldehyde is shown to both reduce the antigenicity of tissue xenograft bioprostheses and increase tissue stability (Refs. 10 & 12). Glutaraldehyde alone has not been shown to affect or reduce the calcification rate of the bioprosthesis.

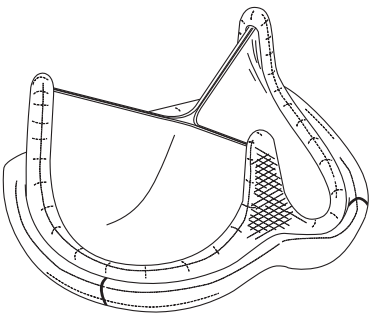
The frame is designed to be compliant at the orifice as well as at the commissures. The compliance of the commissure supports is intended to reduce the loading shock at the valve commissures and free margin of the leaflets (Ref. 42). The compliance of the orifice is intended to reduce the stress on the leaflet. The compliant orifice concept is based on the physiology and mechanics of natural heart valves and reported experience with implantation of unstented homografts (Refs. 5 & 7).

The lightweight wireform frame is made of Elgiloy, a corrosion-resistant alloy, chosen because of its superior spring efficiency and fatigue-resistant characteristics, and is covered with a woven polyester fabric.

A thin Elgiloy/polyester film laminate band surrounds the base of the wireform frame providing structural support for the orifice. To this frame is attached a soft, silicone-rubber suture ring that is covered with a porous, seamless polytetrafluoroethylene cloth to facilitate tissue ingrowth and encapsulation. The aortic sewing ring has been scalloped to conform to the natural aortic root. The compliant nature of the suture ring facilitates coaptation between the bioprosthesis and an often irregular or calcific tissue bed.

An integral valve holder is attached to the valve by means of sutures to facilitate handling and suturing the valve during implantation. The holder is easily detached by the surgeon (see **11.2 Handling and Preparation Instructions**).

The sewing ring diameter and profile height on the Magna Ease aortic bioprosthesis has been reduced to facilitate implantation in patients with small aortic roots. The sewing ring has three equally spaced markers to aid in orientation.



Model 3300TFX PERIMOUNT Magna Ease Aortic Bioprosthesis

2.0 Indications for Use

Pericardial valves are indicated for use in patients suffering from valvular heart disease. Aortic valvular heart disease is a condition involving any of the following: obstruction of the aortic heart valve or stenosis; leakage of the aortic valve, known as regurgitation, incompetence, or insufficiency; and combinations of the two, sometimes referred to as mixed disease or combined lesions.

Aortic valvular heart disease may be caused by any number of factors, including congenital abnormalities, infection by various microorganisms, degenerative calcification, and rheumatic heart disease.

Pericardial valves are used particularly in those patients for whom long-term anticoagulation is contraindicated or who may be difficult to maintain on anticoagulation therapy.

The Magna Ease aortic bioprosthesis is intended for use in patients whose aortic valvular disease is sufficiently advanced to warrant replacement of their natural valve with a prosthetic one. It is also intended for use in patients with a previously implanted aortic valve prosthesis that is no longer functioning adequately and requires replacement. In the latter case, the previously implanted prosthesis is surgically excised and replaced by the replacement prosthesis. The bioprosthesis can be implanted in either the supra-annular or intra-annular position.

3.0 Contraindications

Do not use if 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, non-pyrogenicity, 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. Such action could lead to illness or an adverse event, as the device may not function as originally intended.

DO NOT RESTERILIZE THE BIOPROSTHESIS 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 BIOPROSTHESIS TO EXTREME HEAT. Exposure of the bioprosthesis to extreme temperatures will render the device unfit for use. 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 monitor the temperature that the device is exposed to during transit and storage. If the indicator displays any reading other than "OK" do not use the bioprosthesis.

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

DO NOT USE the bioprosthesis if expiration date has elapsed. There are no data to support the function and performance of the device beyond the expiration date.

DO NOT USE the bioprosthesis if the container is leaking, damaged, or the glutaraldehyde solution does not completely cover the bioprosthesis. Failure to maintain tissue moisture may lead to compromised sterility and/or bioprosthesis function.

DO NOT EXPOSE the bioprosthesis 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 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. Failure to maintain tissue moisture may lead to compromised bioprosthesis function.

DO NOT PASS CATHETERS, transvenous pacing leads, or any surgical instrument across the bioprosthesis with the exception of a surgical mirror used to examine suture placement. Other surgical devices may cause 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. Such action could lead to illness or an adverse event, as the device may not function as originally intended.

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

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- 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.

As with any implanted device, there is potential for an immunological response. Some components of the model 3300TFX are a metal alloy that contains cobalt, chromium, nickel, molybdenum, manganese, carbon, beryllium and iron. Care should be exercised in patients with hypersensitivities to these materials. This device was not made with natural rubber latex, but may have been produced in a latex-containing environment.

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. 1).

Adequate rinsing with physiological saline, as described in the Technique section, is mandatory before implantation to reduce the glutaraldehyde concentration. 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

- The outside of the jar is not sterile and must not be placed in the sterile field.
- Adequate rinsing with physiological saline must be performed before implantation to reduce the glutaraldehyde concentration.
- 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.

- The Magna Ease aortic bioprosthesis has a unique configuration designed to fit above the patient annulus or within the annulus. The surgeon should be familiar with the recommendations for proper sizing and placement in the supra-annular or intra-annular position. Refer to the Device Implantation section (11.3) for further details.
- Handle the bioprosthesis only with Edwards Lifesciences accessories. Only Edwards sizers should be used during the selection of the bioprosthesis size; other sizers may result in improper bioprosthesis selection.
- **When choosing a bioprosthesis for a given patient, the size, age, and physical condition of the patient in relation to the size of the prosthesis must be taken into consideration to minimize the possibility of obtaining a suboptimal hemodynamic result. The selection of a bioprosthesis, however, must ultimately be made by the physician on an individual basis after carefully weighing all of the risks and benefits to the patient.**
- Due to the relative flexibility of the frame, **care must be exercised to prevent folding or deformation of the stent** that may lead to regurgitation, altered hemodynamics, and/or leaflet disruption rendering the bioprosthesis incompetent. In this regard oversizing must be avoided.
- The spacing of the sutures in the remnant of the valvular orifice and the prosthesis suture ring must be carefully matched to avoid folding of the leaflets or distortion of the orifice. Edwards Lifesciences has received reports in which individual mattress sutures, spanning a distance of 10 to 15 mm, produced a pursestring effect causing compression of the valve orifice.
- 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. Cases have been reported in which bioprostheses developed severe regurgitation and had to be replaced as a result of wear due to contact with sutures (Ref. 2).
- Unlike rigid mechanical valves, the stent wall is soft and will not resist needle penetration. Accordingly, extreme care must be exercised when placing sutures through the sewing margin to avoid penetration of the side wall of the stent and possible laceration of the leaflet tissue.
- 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 the commissure, which would interfere with proper valvular function.
- The stent of the aortic bioprosthesis is symmetrical, and the commissure supports (struts) are equally spaced. The struts should correspond to the remnants of the natural commissures so as not to obstruct the coronary ostia.
- 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. This tag should not be detached from the bioprosthesis until implant is imminent. Care should be exercised to avoid cutting or tearing the suture ring cloth during removal.
- 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.
- Based on reports in the literature on tissue valves (Refs. 3, 18, 23, 26, 48, 49, & 54), there appears to be an increased incidence of leaflet calcification in patients under the age of 20. When feasible, repeated intravenous injections containing calcium should be avoided during the postoperative period, and excessive milk or dairy product consumption should be avoided in children. Animal research studies (Ref. 11) show that a high systemic calcium level can lead to early calcification.

6.0 Adverse Events

6.1 Observed Adverse Events

As with all prosthetic heart valves, serious adverse events, sometimes leading to death, may be associated with the use of tissue valves. In addition, adverse events due to individual patient reaction to an implanted device, or to physical or chemical changes in the components, particularly those of biological origin, may occur at varying intervals (hours or days), necessitating reoperation and replacement of the prosthetic device.

Adverse events associated with the use of Carpentier-Edwards PERIMOUNT pericardial bioprostheses compiled from the literature and from reports received through the product surveillance system in accordance with the United States (Federal) regulations establishing Good Manufacturing Practices, section 820.198, include stenosis, regurgitation through an incompetent valve, perivalvular leak, endocarditis, hemolysis, thromboembolism, thrombotic obstruction, bleeding diatheses related to the use of anticoagulant therapy, and malfunctions of the valve due to distortion at implant, fracture of the Elgiloy wireform, or physical or chemical deterioration of valve components. Types of tissue deterioration include infection, calcification, thickening, perforation, degeneration, suture abrasion, instrument trauma, and leaflet detachment from the valve stent posts. These complications may present clinically as abnormal heart murmur, shortness of breath, exercise intolerance, dyspnea, orthopnea, anemia, fever, arrhythmia, hemorrhage, transient ischemic attack, stroke, paralysis, low cardiac output, pulmonary edema, congestive heart failure, cardiac failure, and myocardial infarct.

Note: Based on reports in the literature on tissue valves (Refs. 3, 18, 23, 26, 36, 48, 49, & 54), there appears to be an increased incidence of leaflet calcification in patients under the age of 20. In this regard, animal research studies (Ref. 11) show that a high systemic calcium level can lead to early calcification. Furthermore, at least one published report describes a potential relationship between the consumption of daily calcium supplements and early leaflet calcification in an adult (Ref. 34). When feasible, repeated intravenous injections containing calcium should be avoided during the postoperative period; and excessive milk or dairy product consumption should be avoided in children. There are no clinical data presently available demonstrating increased resistance of Magna Ease aortic bioprostheses to calcification as compared to other commercially available bioprostheses.

6.2 Potential Adverse Events

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

- Angina
- Cardiac arrhythmias
- Endocarditis
- Local and/or systemic infection
- Heart failure
- Hemolysis
- Hemolytic anemia
- Hemorrhage

- Myocardial infarction
- Prosthesis leaflet entrapment (Impingement)
- 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

For a patient/user/third party in the European Economic Area; if, during the using of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and your national competent authority, which can be found at https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

7.0 Clinical Studies

7.1 Pre-Approval Patient Cohort

Clinical data, available on 719 patients requiring isolated aortic valve replacement (AVR) with the Model 2700 Carpentier-Edwards pericardial bioprosthesis with mean follow-up of 3.9 years, indicate overall actuarial survival rate at 6 years of 73.7% ±2.0%. Clinical data, available on 70 patients requiring double valve replacement (DVR) with mean follow-up of 3.7 years, indicate overall actuarial survival rate at 6 years of 67.2% ±6.5%. This pre-approval patient cohort data was collected from the period between August 1981 to January 1989.

In the isolated AVR population, there were a total of 455 (63.3%) males and 264 (36.7%) females with a mean age at implant (± standard deviation) of 64 (±12.4) years and a range of 18 to 90 years. The indications for valve replacement were stenosis (63.4%), regurgitation (16.3%), mixed disease (15.3%) and previous prosthetic aortic valve dysfunction (5.0%).

In the DVR population, there were a total of 24 (34.3%) males and 46 (65.7%) females with a mean age (± standard deviation) of 62.9 (±12.7) years and a range of 31 to 94 years. The indications for valve replacement were stenosis (45.7%), regurgitation (25.7%), mixed disease (21.4%) and previous prosthetic aortic valve dysfunction (7.4%).

The follow-up methods used at each clinic included hospital visits, office visits and contact by telephone or letter with either the patient, the patient's family or local doctor.

Table 1 summarizes the operative and postoperative complication rates for the isolated AVR and DVR populations. The operative rates are based on 719 patients for the isolated AVR population and on 70 patients for the DVR population. The postoperative rates are based on 2767.9 and 255.8 years of follow-up occurring >30 days after implant for the isolated AVR and DVR populations respectively.

Table 2 presents, by valve size, the mean gradients reported in echocardiograms performed on patients in this study population.

Information on preoperative and postoperative NYHA Functional Class was gathered for the isolated AVR population. In 220 patients the NYHA was not reported (171 patients expired and 49 patients not available). Of the 499 patients with reported preoperative and postoperative NYHA Functional Class at the last available follow up, 10 patients (2.0%) got worse, 59 patients (11.8%) remained the same and 430 patients (86.2%) improved.

Table 3 presents data comparing preoperative NYHA Functional Class to postoperative NYHA Functional Class at the last available follow up.

7.2 Post-Approval Patient Cohort

Edwards continues to follow a post-approval cohort of 267 patients with isolated valve replacements (AVR) (Model 2700) from four centers of the original clinical trial for the Carpentier-Edwards PERIMOUNT pericardial bioprosthesis since November 1981. The population is comprised of 171 (64%) males and 96 (36%) females. The mean age (± standard deviation) of these patients at the time of implant was 64.9 ±11.8 years and ranged from 21 to 86 years. A total of 140 deaths occurred between 1981 and 1994. Thirty-one (22.1%) of the 140 deaths were determined to be valve-related. The actuarial valve-related survival is 83% at 12 years. In the postoperative period, 16 patients required valve explants. One event occurred as a result of perivalvular leak, two due to endocarditis/sepsis and 13 were due to valve dysfunction. The actuarial explant-free rate is 90% at 12 years.

The follow-up methods used at each clinic included hospital visits, office visits, and contact by telephone or letter with either the patient, the patient's family, or local doctor.

Table 4 summarizes operative (<30 days) and postoperative (≥30 days) valve-related complication rates. The postoperative linearized complication rates are based on 2131.5 patient years of follow-up. The Carpentier-Edwards PERIMOUNT pericardial bioprosthesis was implanted in this cohort from September 1981 through December 1983 with a mean follow-up of 8.1 years. The 267 patients in the cohort have a total of 2152 patient years of follow-up. Of the 127 patients eligible for follow-up (not considered dead or explanted prior to the 1994 update) 17 (13.4%) patients are considered lost to follow-up. In the operative period, there were eight thromboembolic events, four hemorrhagic anticoagulation complications (HAC), one perivalvular leak and one valve dysfunction. In the postoperative period there were 31 thromboembolic events, eight hemorrhagic anticoagulation complications, four perivalvular leaks, two incidences of hemolysis, seven cases of endocarditis and 53 incidents of valve dysfunction in 38 patients. Valve dysfunction included 23 patients with hemodynamic valve dysfunction, 13 required reoperation/explant, and valve dysfunction was the cause of death in two patients.

While overall patient survival is 45% at 12 years, freedom from valve related deaths is 83%. These results suggest a patient population which presents with morbidity from many **non-valve** related disorders. In addition, 12-year complication rates for freedom from explants, thromboembolism, endocarditis and HAC were above 80%. The 12-year freedom from valve dysfunction is 78%. This rate includes all forms of dysfunction, including PV leak, regurgitation, stenosis, leaflet disruption, calcification and unspecified dysfunction.

Improvement in NYHA functional classification has also been demonstrated postoperatively. Forty-five percent of the patients are in NYHA Functional Class I at 12 years post implant with the Carpentier-Edwards pericardial valve.

This data was compiled as of July 1994 from a multi-center clinical trial conducted by Edwards Lifesciences. Follow-up on this post-approval cohort is continuing, and periodic updates will be available by contacting Edwards Lifesciences LLC, Cardiovascular Surgery Marketing Department, One Edwards Way, Irvine, CA 92614.

8.0 Individualization of Treatment

It is recommended that prophylactic antibiotic therapy be given to patients undergoing dental or other procedures, which are potentially bacteremic in order to minimize the risk of endocarditis.

Some medical professional societies recommend anticoagulant therapy unless contraindicated, during the first 3 months after bioprosthetic aortic valve implantation. Such postoperative anticoagulant therapy should be determined on an individual basis.

Long-term low dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves. Long-term anticoagulant therapy, unless contraindicated, is recommended for all patients with bioprosthetic valves who have risk factors for thromboembolism.

Careful and continuous medical follow-up is advised so that valve related complications can be diagnosed and properly managed.

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.

In the presence of conditions affecting calcium metabolism or when calcium containing chronic drug therapies are used, the use of a mechanical prosthesis as an alternative should be considered. This is also true in patients on a high calcium diet, and in patients who are on maintenance hemodialysis.

8.1 Specific Patient Populations

The safety and effectiveness of the PERIMOUNT Magna Ease aortic bioprosthesis has not been established for the following specific populations because it has not been studied in these populations:

- patients who are pregnant or lactating;
- patients with chronic renal impairment or calcium metabolism disorders;
- patients with active endocarditis or myocarditis;
- patients with aneurysmal aortic degenerative conditions (e.g., cystic medial necrosis, Marfan's syndrome);
- children or adolescents.

9.0 Patient Counseling Information

Careful and continued 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.

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 an implant when seeking care.

10.0 How Supplied

10.1 Available Models and Sizes

The Magna Ease aortic bioprosthesis is available in labeled sizes 19, 21, 23, 25, 27, and 29 mm (reference Table 1 for nominal specifications).

10.2 Packaging

The Magna Ease aortic 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 products which have been exposed to transient temperature extremes. Please refer to the Storage section for product storage conditions. 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 Magna Ease aortic bioprosthesis should be stored at 10 °C to 25 °C (50 °F–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.

CAUTION: 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 Magna Ease aortic bioprosthesis. The techniques for implanting this bioprosthesis are similar to those used for supra-annular or intra-annular placement of any stented aortic bioprostheses.

11.2 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.

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 a Magna Ease aortic 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. No attempt should be made to resterilize a Magna Ease aortic bioprosthesis.

CAUTION: The bioprosthesis and glutaraldehyde storage solution are sterile. The outside of the jar is not sterile and must not be placed in the sterile field.

Remove the seal and screw-lid from the jar. The jar should contain enough buffered glutaraldehyde storage solution to cover the prosthesis. The contents of the jar should be handled in an aseptic manner to prevent contamination.

Using gloved hand, attach the handle to the bioprosthesis holder while the bioprosthesis is still in the container. To do this, align the handle with the threaded hole in the bioprosthesis holder and turn clockwise until a positive resistance is felt. Aligning the handle will ensure a proper and secure attachment. Using handle remove clip and bioprosthesis from jar. Using gloved hand grasp clip and continue to rotate the handle until fully engaged as shown in Figure 1. **Do not grasp the bioprosthesis**. Be careful not to exert too much pressure while turning so as to push the bioprosthesis off the clip and damage the bioprosthesis.

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

Note: The model 1111 or model 1126 (single use) handle is recommended for use with the aortic bioprosthesis.

Remove the clip by grasping the clip edge and slide off parallel to bioprosthesis (Figure 2). Discard the clip.

CAUTION: Unprotected forceps must never be used in handling these bioprostheses. The leaflet tissue should never be handled.

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.

To rinse the bioprosthesis, place the bioprosthesis in a minimum of 500 ml of sterile physiological saline solution. Be sure the saline solution completely covers the bioprosthesis and holder. Do not rinse with the clip/retainer attached. With the bioprosthesis 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). Discard the rinse solution. Repeat this process once using new saline solution for a minimum of 1 minute. The valve should be left in the final rinse solution until needed to prevent the tissue from drying.

CAUTION: Do not allow the tissue to come in contact with the bottom or sides of the rinse basin during agitation or swirling of the bioprosthesis. Care must be taken to ensure that the I.D. tag does not come in contact with the tissue and injure it. No other objects should be placed in the rinse basin.

Inspect the bioprosthesis and remove the serial number tag just prior to implantation.

11.3 Device Implantation

Because of the complexity and variation in the surgical procedure of cardiac valve replacement, the choice of surgical technique, appropriately modified in accordance with the previously described **Warnings, Precautions, and Techniques**, is left to the discretion of the individual surgeon. In general, the following steps should be used:

Step	Procedure
1	Surgically remove the diseased or damaged valve leaflets and all associated structures deemed necessary by the surgeon.
2	Surgically remove any calcium from the annulus to ensure proper seating of the sewing ring.
3	Measure the size of the annulus using only Carpentier-Edwards sizers, model 1133 aortic (Figures 4-6). The model 1133 sizers can be used to measure for either supra-annular or intra-annular placement, depending on surgeon preference. **Supra-annular sizing and implantation:** Using supra-annular technique, the sewing ring of the valve is placed above the annulus, maximizing valve orifice area. A larger valve size can often be implanted using a supra-annular technique compared to an intra-annular technique. This increase in prosthetic valve size provides improved hemodynamic performance. For optimal implantation of the valve in the supra-annular position, the sizer should be parallel with the plane of the annulus and the following sizing technique should be used: a) Using the model 1133 sizer, select the cylindrical end of the largest diameter sizer that comfortably fits in the patient's annulus (Figure 7). b) Once you have verified the appropriate cylindrical end, use the replica end of the same sizer to verify that the sewing ring will fit comfortably on top of the annulus (Figure 8). c) Determine if upsizing of the valve is possible by using the replica end of the **next larger sizer** (Figure 9). Ensure that the coronary ostia are not obstructed and that the valve stent posts do not interfere with the aortic wall at the sinotubular junction (Figure 10). If this larger size replica end fits comfortably, implant this size of the Magna Ease aortic bioprosthesis. If this larger size replica end does not fit comfortably, implant the valve size identified by Sub-Step b. A suture technique resulting in supra-annular placement of the valve, such as a horizontal mattress technique, should be employed. **Intra-annular sizing and implantation:** Using intra-annular technique, the entire valve including the sewing ring is placed inside the annulus. Either the cylindrical or valve replica end of the model 1133 sizer can be used for intra-annular sizing. For proper sizing, the sizer should be parallel with the plane of the annulus and the entire sizer, including the simulated sewing ring portion, should pass through the annulus (Figure 11-13). A suture technique resulting in intra-annular placement of the valve, such as an everting mattress technique, should be employed.

Step	Procedure
4	Suture the valve in place using an appropriate suture technique that avoids the potential problems noted under **5.0 Precautions.**

WARNING: 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 bioprosthesis moist during the implant procedure.

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

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

11.3.1 Handle/Holder Removal

The integral holder and attached handle are removed as a unit at the completion of the suturing procedure in the following manner (see Figure 3):

Step	Procedure
1	Using a scalpel or scissors as shown, cut each of the three exposed sutures that are on the top of the holder. **CAUTION: Avoid cutting or damaging the stent or delicate leaflet tissue when cutting the sutures.**
2	When all three attaching sutures have been properly cut, remove the handle/holder assembly, along with the attaching sutures, from the bioprosthesis as a unit.
3	Following surgery, remove the holder from the handle and discard the holder. If using model 1111 handle clean and sterilize the handle before each use.

11.4 Accessories

Sizers

The use of a sizing instrument facilitates selection of the correct size valve for implantation. Model 1133 sizers are designed to permit direct observation of their fit within the annulus. The model 1133 sizer was developed to facilitate accurate sizing of the Magna Ease aortic bioprosthesis in a wide range of patients. Each sizer consists of a handle with a different sizer configuration at each end (Figure 4). On one side of the handle is a cylindrical end with an integrated lip that reflects the valve sewing ring geometry (Figure 5). On the other side of the handle is a valve replica end that reflects the valve sewing ring geometry as well as the height and location of the stent posts (Figure 6). A sizer is available for each size of the Magna Ease aortic bioprosthesis (19, 21, 23, 25, 27, and 29 mm).

CAUTION: Do not use other manufacturers' valve sizers, or sizers for other Edwards Lifesciences valve prostheses, to size the aortic bioprosthesis.

Valve Holder and Handle

The handle/holder assembly consists of two components: an integral disposable part that is physically mounted to the valve by the manufacturer, and a **malleable** handle (reusable model 1111 or disposable model 1126 for single use) that is attached to the holder at the time of surgery.

CAUTION: The model 1126 disposable handle is supplied sterile for single use and must not be resterilized.

11.5 Accessories Cleaning and Sterilization Instructions

Refer to the Instructions for Use supplied with the reusable accessories for cleaning and sterilization instructions.

The model 1111 handle and the model 1133 sizers are supplied nonsterile and must be sterilized before using. The handles and sizers must be cleaned and resterilized prior to each use.

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

11.6 Return of Explanted Bioprostheses

Edwards Lifesciences is extremely interested in obtaining recovered clinical specimens of Magna Ease aortic bioprostheses for analysis. Please contact your local bioprosthesis specialist for return of recovered bioprostheses. The explanted bioprostheses should be placed into a suitable histological fixative such as 10% formalin or 2% glutaraldehyde 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 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 bioprosthesis 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.

12.3 Safety in the Magnetic Resonance (MR) Environment

MR Conditional

Non-clinical testing has demonstrated that the Carpentier-Edwards PERIMOUNT Magna Ease pericardial aortic bioprosthesis, model 3300TFX 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 magnetic 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 Ease pericardial aortic bioprosthesis, model 3300TFX 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 25.5 mm from the Carpentier-Edwards PERIMOUNT Magna Ease pericardial aortic bioprosthesis when imaged with a gradient echo pulse sequence and approximately as far as 12.5 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.

This product is manufactured and sold under at least one or more of the following U.S. Patents: US-Patent Nos. 6,413,275; 6,416,547; 8,202,314; 8,366,769; 8,632,608; and 9,439,762; and corresponding foreign patents. Likewise, additional patents pending.

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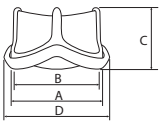
Table 1: Nominal Specifications (mm)

Carpentier-Edwards PERIMOUNT Magna Ease Aortic Pericardial Bioprosthesis, Model 3300TFX



Size	19 mm	21 mm	23 mm	25 mm	27 mm	29 mm
A. Stent Diameter (Wireform)	19	21	23	25	27	29
B. Internal Diameter (Stent I.D.)	18	20	22	24	26	28
C. Profile Height	13	14	15	16	17	18
D. External Sewing Ring Diameter	24	26	28	30	32	34
– Tissue Annulus Diameter	19	21	23	25	27	29

Note: For sizing, see surgical procedure recommendations.

Table 2: Summary of Complication Rates, Model 2700

	Isolated AVR Population			DVR Population		
Complication	**Operative % of Pts.**	**Post-Operative % Per Pt. Yr.**	**% Event-Free at Six Years (Standard Error)**	**Operative % of Pts.**	**Post-Operative % Per Pt. Yr.**	**% Event-Free at Six Years (Standard Error)**
Death	4.7	4.6	73.5 (2.0)	12.9	4.2	67.2 (6.5)
Explant	0	0.3	98.5 (1.0)	0	0.8	NA*
Valve Related Reoperation	0.7	0.1	99.8 (0.4)	0	0	NA*
All Reoperation	22.4	1.8	75.4 (1.8)	34.3	2.3	NA*
Valve Related Thromboembolism	3.1	1.5	91.4 (1.1)	1.4	5.1	NA*
All Thromboembolism	5.0	2.4	84.9 (1.6)	5.7	6.6	NA*
Endocarditis	0.6	0.8	95.8 (0.9)	1.4	1.5	NA*
Valve Dysfunction	0.1	0.7	96.0 (1.1)	0	0.4	NA*
Perivalvular Leak	0.1	0.3	98.8 (0.5)	0	1.2	NA*
Hemorrhagic Anticoagulation Complication	1.4	0.4	96.4 (1.1)	4.3	2.3	NA*
Hemolysis	0	0.2	99.1 (0.4)	0	0.4	NA*
Valve Thrombosis	0	0	100.0 (0)	0	0.4	NA*

* NA = Not Applicable

Table 3: Postoperative Echocardiography Results, Model 2700

	Valve Size						
	19 mm	**21 mm**	**23 mm**	**25 mm**	**27 mm**	**29 mm**	**Total**
Total N	12	22	15	8	3	3	63
Avg. Months Postoperative	28.6 ± 7.2	34.9 ± 8.6	36.9 ± 9.2	39.9 ± 7.6	31.4 ± 15.9	15.3 ± 12.2	34.6 ± 9.2
Velocity (M/sec) mean ± S.D.	2.80 ± 0.49	2.56 ± 0.46	2.36 ± 0.42	2.15 ± 0.56	2.09 ± 0.27	2.08 ± 0.1	2.46 ± 0.50
n =	12	21	15	7	3	3	61
range	1.90 - 3.60	1.90 - 3.90	1.39 - 2.86	1.00 - 2.60	1.90 - 2.40	2.05 - 2.10	1.00 - 3.90
Peak Instantaneous							
Gradient (mmHg) mean ± S.D.	32.22 ± 11.08	27.04 ± 10.49	23.00 ± 7.30	19.50 ± 8.16	17.60 ± 4.70	14.4 ± 0.58	25.67 ± 10.14
n =	12	21	15	7	3	3	61
range	14.40 - 51.80	14.40 - 60.80	7.70 - 32.70	4.00 - 27.00	14.40 - 23.00	13.95 - 15.06	4.00 - 60.80

Table 4: Effectiveness Outcomes, Functional NYHA, Model 2700

Preoperative NYHA Functional Class	Postoperative NYHA Functional Class					
	I	II	III	IV	Expiration	Not Available
I	18	19			9	
II	140	37			35	15
III	181	48	4	1	72	24
IV	43	16	2		53	2
Not Available	5	1			2	2

Table 5: Summary of all Valve-Related Complication Rates (N = 267), Model 2700

	Operative Period (≤30 Days) % of Pts.		Postoperative Period (>30 Days) % Per Pt. Year	
Complication	**No. of Incidences**	**%**	**No. of Incidences**	**%**
Thromboembolism / Thrombus	8	3.0	31	1.45
Endocarditis	0	0	7	0.33
Valve Dysfunction	1	0.37	34	1.60
Perivalvular Leak	1	0.37	4	0.19
Hemorrhagic Anticoagulation Complication	4	1.50	8	0.38
Hemolysis	0	0	2	0.09
Reoperation / Explant	0	0	16	0.75
Reoperation - Other	3	1.12	1	0.05
Expiration	1	0.37	30	1.41
Totals	**18**		**133**	

Figures

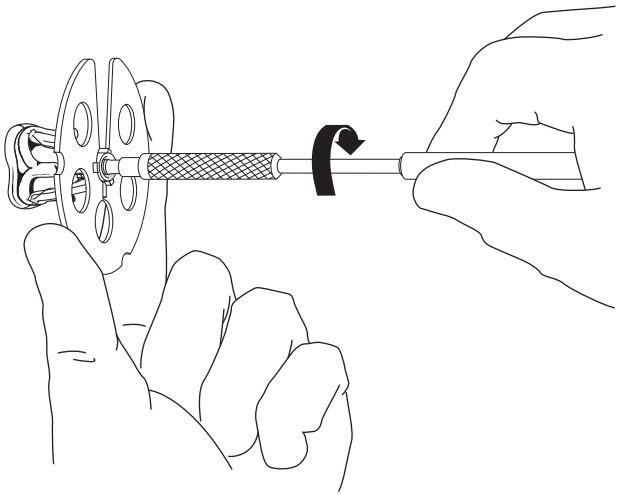


Figure 1: Aortic

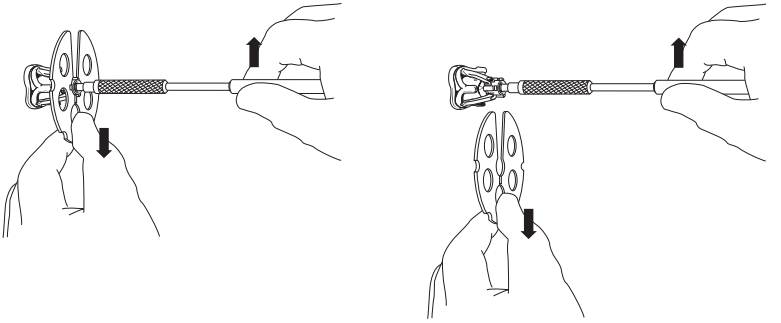


Figure 2: Aortic

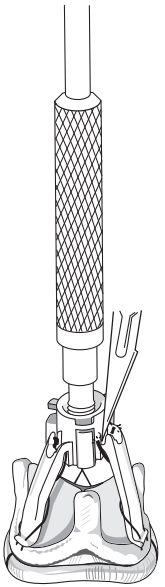


Figure 3: Aortic

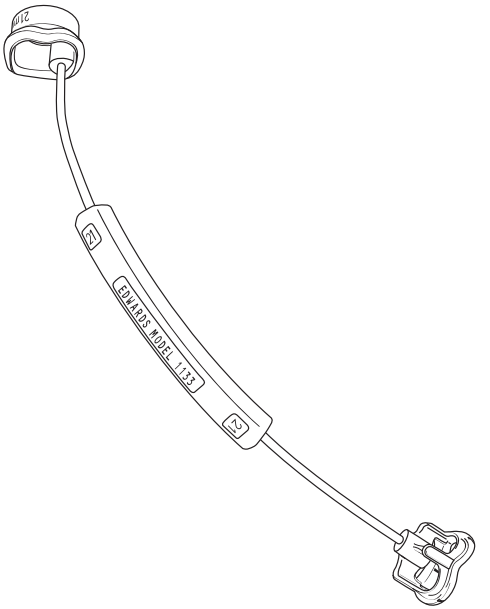


Figure 4: Aortic Sizer

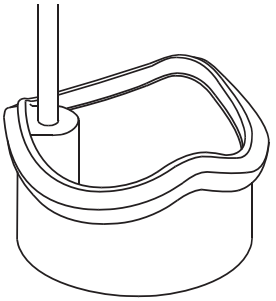


Figure 5: Cylindrical Sizer

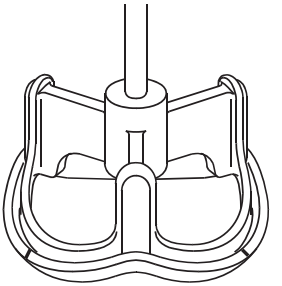


Figure 6: Replica Sizer

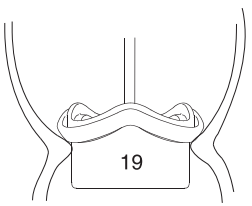


Figure 7: Supra-Annular Measurement

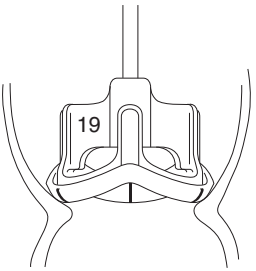


Figure 8: Supra-Annular Measurement

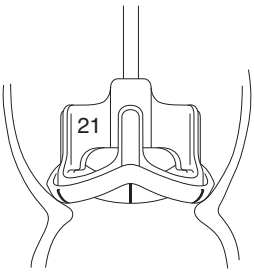


Figure 9: Supra-Annular Measurement

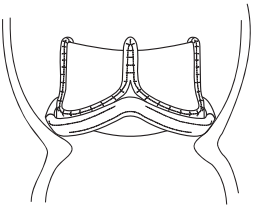


Figure 10: Supra-Annular Placement

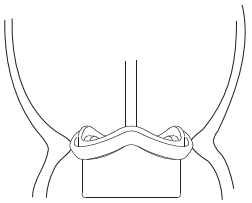


Figure 11: Intra-Annular Measurement

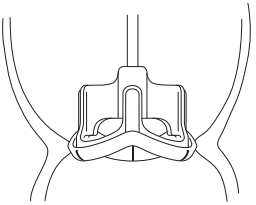


Figure 12: Intra-Annular Measurement

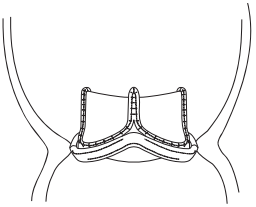
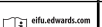


Figure 13: Intra-Annular Placement

Symbol Legend

	English		English		English
	Caution	SN	Serial Number	SZ	Size
	Do Not Freeze - Store between 10 °C and 25 °C	STERILE	Sterile	EC REP	Authorized representative in the European Community
	Do not re-use		Do not use if package is damaged		MR Conditional
	Consult instructions for use		Use-by date		Conformité Européenne (CE Mark)
	Consult instructions for use on the website		Non-pyrogenic		Use product if indication is shown
REF	Catalogue Number		Manufacturer		Do not use product if indication is shown
	Date of manufacture	#	Quantity		

Note: Not all symbols may be included in the labeling of this product.

EC REP

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