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

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 Ease pericardial aortic 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. It is available in sizes 19, 21, 23, 25, 27, and 29 mm. The bioprosthesis is treated with the Carpentier-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. 1 & 2). Glutaraldehyde alone has not been shown to affect or reduce the calcification rate of the bioprosthesis.

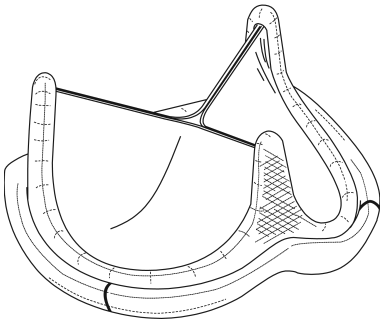
The frame is designed to be compliant at the orifice as well as at the commissures. The compliance of the commissure supports is intended to reduce the loading shock at the valve commissures and free margin of the leaflets (Ref. 3). The compliance of the orifice is intended to reduce the stress on the leaflets. The compliant orifice concept is based on the physiology and mechanics of natural heart valves and reported experience with implantation of unstented homografts (Refs. 4 & 5).

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 sewing 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 sewing ring facilitates coaptation between the bioprosthesis and an often irregular or calcific tissue bed.

An integral bioprosthesis holder is attached to the bioprosthesis by means of sutures to facilitate handling and suturing the bioprosthesis during implantation. The holder is easily detached by the surgeon. (See **12.5 Device Implantation.**)

To facilitate implantation in patients with small aortic roots, the Magna Ease aortic bioprosthesis has a low profile height. The sewing ring has three, equally-spaced suture markers at the cusp centers to aid in bioprosthesis orientation and suture placement.



Model 3300TFX PERIMOUNT Magna Ease Aortic Bioprosthesis

2.0 Indications for Use

The Carpentier-Edwards PERIMOUNT Magna Ease pericardial bioprosthesis model 3300TFX is indicated for patients who require replacement of their native or prosthetic aortic 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 Specific Patient Populations

The safety and effectiveness of the Magna Ease aortic bioprosthesis model 3300TFX 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, and young adults.

CAUTION: Based on reports in the literature on tissue valves (Refs. 6, 7, 8, 9 & 10), 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.

5.0 Warnings

For Single Use Only

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. 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. Please refer to Storage section (11.2) for further instructions.

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

DO NOT USE the bioprosthesis if the 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 or transvenous pacing leads across the bioprosthesis since they may cause tissue damage. Care must be exercised when passing a surgical instrument across the bioprosthesis to avoid 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 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 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 the Magna Ease aortic bioprosthesis. Serious adverse events, sometimes leading to replacement of the bioprosthesis and/or death, may be associated with the use of prosthetic valves (see **7.0 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 8.0 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 anticoagulation 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. 12).

Adequate rinsing with physiological saline is mandatory before implantation to reduce the glutaraldehyde concentration (see **12.4 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.

6.0 Precautions

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

7.0 Adverse Events

7.1 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 Magna Ease 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 anticoagulation 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 infarction.

Note: Based on reports in the literature on tissue valves (Refs. 6, 7, 8, 9 & 10), 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. 13). 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 Carpentier-Edwards PERIMOUNT Magna Ease aortic bioprostheses to calcification as compared to other commercially available bioprostheses.

7.2 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
- 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

8.0 Clinical Studies

Pre-Approval Patient Cohort

Clinical data, available on 719 patients requiring isolated aortic valve replacement (AVR) with the model 2700 Carpentier-Edwards PERIMOUNT 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%. These pre-approval patient cohort data were 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 2 summarizes the operative and post operative 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 3 presents, by valve size, the postoperative echocardiography results of 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 Functional Class 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 4 presents data comparing preoperative NYHA Functional Class to postoperative NYHA Functional Class at the last available follow-up.

Post-Approval Patient Cohort

Edwards has followed 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 2,407 patient years of data were available for analysis (2,386 late patient years). Mean follow-up was 9.0 ± 5.5 years, with a maximum of 20.3 years. A total of 189 deaths occurred between 1981 and 1994. Forty-eight (25.3%) of the 189 deaths were determined to be valve-related. 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 5 summarizes the freedom from complication rates at 20 years. Patient status as of the last follow-up interval included 189 expired (70.8%), 10 alive (3.8%), 46 explanted (17.2%), and 22 lost to follow-up (8.2%).

There were a total of 48 valve-related expirations in this patient population; 1 valve-related expiration occurred in the operative period and consisted of bleeding. Twenty-eight postoperative valve-related expirations included 5 due to thromboembolism, 4 due to endocarditis/sepsis, 3 due to structural valve deterioration and 1 due to bleeding. There were 15 other expirations that were considered to be valve-related because of lack of information or because the expiration was classified as valve-related by the investigator. The actuarial freedom from valve-related expiration was 67.9 ± 6.6% at 20 years. Nineteen additional expirations were due to either unknown causes or sudden death and might have been valve related. These deaths were conservatively classified as valve related; accordingly, the resulting actuarial freedom from valve-related expiration was 55.4 ± 6.4% at 20 years.

Improvement in NYHA functional classification has also been demonstrated postoperatively. As of the latest follow-up evaluation, 108 patients (44.8%) were in NYHA Functional Class I.

These data were compiled from a multi-center clinical trial conducted by Edwards Lifesciences. For additional information on this trial, please contact Edwards Lifesciences LLC, Heart Valve Therapy Marketing Department, One Edwards Way, Irvine, CA 92614.

Confirmatory Study

From August 2003 through January 2004, 60 patients requiring aortic valve replacement (AVR) were implanted with the Carpentier-Edwards PERIMOUNT Magna aortic bioprosthesis, model 3000, from five institutions (two European and three Canadian). Shortly thereafter, the clinical protocol was amended to allow implantation with the Carpentier-Edwards PERIMOUNT Magna aortic bioprosthesis, model 3000TFX, and to add three US institutions. Subsequently, 193 additional patients were implanted with the model 3000TFX from December 2004 through December 2006. The model 3000TFX differs from the model 3000 in that the model 3000TFX is treated with the ThermaFix process.

In the model 3000TFX population, there were a total of 116 males (60.1%) and 77 females (39.9%) with a mean age at implant of 72.0 (± 8.59 SD) years and an age range from 26 to 89 years. The main indication for valve replacement was stenosis (78.2%) followed by mixed disease (14.5%), and regurgitation (7.3%).

In the combined models 3000 and 3000TFX population, there were a total of 150 males (59.3%) and 103 females (40.7%) with a mean age at implant of 72.2 (± 8.31 SD) years and an age range from 26 to 89 years. Again the major indication for valve replacement was stenosis (77.5%), mixed disease (15.4%), and regurgitation (7.1%).

Patients were evaluated preoperatively, intraoperatively/at discharge, at 3 to 6 months, at 1 year, and annually thereafter. The cumulative follow-up for the model 3000TFX was 167 patient-years, with a mean follow-up of 0.9 years (SD = 0.42, range = 0.0 to 2.1 years); and the cumulative follow-up for both models 3000 and 3000TFX combined was 232 patient-years with a mean follow-up of 0.9 years (SD = 0.42, range = 0.0 to 2.1 years).

Table 6 summarizes early (≤ 30 days) and late postoperative (> 30 days) valve-related adverse event rates for the model 3000TFX and the combined models 3000/3000TFX populations, respectively.

Table 7 illustrates, by valve size, hemodynamic variables reported in echocardiograms at one year performed on patients in the model 3000TFX and the combined model 3000/3000TFX studies.

Table 8 presents the change in NYHA Functional Class from baseline assessment to the 1-year visit. It should be noted that there was a 56.5% improvement in functional class at the 1-year visit for model 3000TFX. For the model 3000/3000TFX combined population, there was a 60.9% improvement in functional class at the 1-year visit.

Several published clinical studies demonstrate the long-term durability of Carpentier-Edwards PERIMOUNT pericardial aortic bioprostheses, the foundation on which the Carpentier-Edwards PERIMOUNT Magna and Magna Ease pericardial aortic bioprostheses are designed (Refs. 14, 15, 16 & 17). Additionally, published data show the Carpentier-Edwards PERIMOUNT Magna aortic bioprosthesis demonstrates exceptional hemodynamic performance, with a very low risk of patient-prosthesis mismatch (Refs. 18, 19, 20, 21, 22 & 23).

9.0 Individualization of Treatment

Bioprosthetic heart valve recipients should be maintained on anticoagulation therapy, except where contraindicated, during the initial stages after implantation as determined by the physician on an individual basis. Long-term anticoagulation 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 ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all the

circumstances presented by that patient (Ref. 12). A bioprosthesis is recommended for AVR in patients of any age who will not take warfarin or who have major medical contraindications to warfarin therapy. Patient preference is a reasonable consideration in the selection of aortic valve operation and valve prosthesis. A mechanical prosthesis is reasonable for AVR in patients under 65 years of age who do not have a contraindication to anticoagulation. A bioprosthesis is reasonable for AVR in patients under 65 years of age who elect to receive this valve for lifestyle considerations after detailed discussions of the risks of anticoagulation versus the likelihood that a second AVR may be necessary (Ref. 12).

10.0 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 Patient Identification Card at all times and to inform their healthcare providers that they have an implant when seeking care.

11.0 How Supplied

11.1 Packaging

The Carpentier-Edwards PERIMOUNT 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 monitor the temperature that the device is exposed to during transit and storage. Upon receipt of the bioprosthesis immediately inspect to see if the indicator displays any reading other than "OK", if so do not use the bioprosthesis. 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 its 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.

If the indicator shows that the bioprosthesis has been exposed to extreme temperatures during transit, do not use the bioprosthesis. Contact the local supplier or representative of Edwards Lifesciences to make arrangements for return authorization and replacement. Any bioprosthesis returned to the company should be shipped in the same styrofoam enclosure in which it was received. 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 the customer's expense.

11.2 Storage

The Carpentier-Edwards PERIMOUNT Magna Ease aortic 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.

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.

12.0 Directions for Use

12.1 Physician Training

The techniques for implanting this bioprosthesis are similar to those used for supra-annular or intra-annular placement of any stented aortic bioprosthesis. No special training is required to implant the Carpentier-Edwards PERIMOUNT Magna Ease aortic bioprosthesis, model 3300TFX.

12.2 Accessories

Sizers

The use of a sizing instrument facilitates selection of the correct size valve for implantation. Model 1133 sizers are fabricated from translucent Polysulfone plastic to permit direct observation of their fit within the annulus. The model 1133 sizer was developed to facilitate accurate sizing of the Carpentier-Edwards PERIMOUNT Magna Ease aortic bioprosthesis in a wide range of patients. Each sizer consists of a handle with a different sizing configuration at each end (Figure 3). On one side of the handle is a cylindrical end with an integrated lip that reflects the bioprosthesis sewing ring geometry (Figure 4). On the other side of the handle is a bioprosthesis replica end that reflects the bioprosthesis sewing ring geometry as well as the height and location of the stent posts (Figure 5). A sizer is available for each size of the Carpentier-Edwards PERIMOUNT Magna Ease aortic bioprosthesis (19, 21, 23, 25, 27, and 29 mm).

Bioprosthesis Holder and Handle

The handle/holder assembly consists of two components: an integral disposable part that is physically mounted to the bioprosthesis 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.

12.3 Accessory Sterilization

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 for signs of wear, such as dullness, cracking or crazing. Replace sizer if any deterioration is observed.

CAUTION: Do not sterilize the sizers, model 1133, and handles, model 1111, in their shipping containers.

Sizers and handles must be removed from their plastic shipping pouches prior to sterilization. Each institution should use procedures that include biological indicators to determine the effectiveness of the sterilization procedure.

CAUTION: Use only the sterilization tray, model TRAY1133, to sterilize the sizers and handles.

The following conditions are recommended:

Autoclave Sterilization:	
Gravity Displacement:	
Wrapped:	
Temperature:	270-279 °F (132-137 °C)
Exposure Time:	10-18 minutes
Unwrapped ("flash"):	
Temperature:	270-279 °F (132-137 °C)
Exposure Time:	3 minutes
Prevacuum:	
Wrapped:	
Temperature:	270-279 °F (132-137 °C)
Exposure Time:	3-18 minutes
Unwrapped ("flash"):	
Temperature:	270-279 °F (132-137 °C)
Exposure Time:	3 minutes

12.4 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.

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.

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 Carpentier-Edwards PERIMOUNT 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 Carpentier-Edwards PERIMOUNT Magna Ease aortic bioprosthesis.

Remove the seal and screw-lid from the jar. The jar should contain enough buffered glutaraldehyde storage solution to cover the bioprosthesis. 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.

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

CAUTION: 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 sewing ring cloth during removal.

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 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 one minute in each of the two previously prepared rinse basins. The bioprosthesis should remain in the second rinse basin until ready for implantation. Adequate rinsing with physiological saline must be performed before implantation to reduce the glutaraldehyde concentration.

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.

CAUTION: Exercise care to avoid cutting or tearing the sewing ring cloth during removal of the serial number tag.

12.5 Device Implantation

The Carpentier-Edwards PERIMOUNT 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.

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

Step	Procedure
1	Surgically remove the diseased or damaged valve leaflets and all associated structures deemed necessary.
2	Surgically remove any calcium from the annulus to ensure proper seating of the sewing ring of the bioprosthesis to avoid damage to the delicate leaflet tissue.
3	Measure the annulus using only the Carpentier-Edwards aortic sizers, model 1133 (Figures 3-5). The model 1133 sizers can be used to measure for either supra-annular or intra-annular placement, depending on surgeon preference. **CAUTION: 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.** **CAUTION: Do not use other manufacturers' valve sizers, or sizers for other Edwards Lifesciences valve prostheses, to size the Carpentier-Edwards PERIMOUNT Magna Ease aortic bioprosthesis.**

12.5.1 Supra-Annular Sizing and Implantation

When a supra-annular technique is utilized, the sewing ring of the bioprosthesis is placed above the annulus, thereby maximizing valve orifice area. A larger bioprosthesis size can often be implanted using a supra-annular technique compared to an intra-annular technique. This increase in bioprosthesis size provides improved hemodynamic performance.

For optimal implantation of the bioprosthesis in the supra-annular position, the sizer should be parallel with the plane of the annulus and the following sizing technique should be used:

Step	Procedure
1	Using the model 1133 sizer, select the cylindrical end of the largest diameter sizer that comfortably fits in the patient's annulus (Figure 6).
2	Once the appropriate cylindrical end has been verified, use the replica end of the same sizer to verify that the sewing ring will fit comfortably on top of the annulus (Figure 7). Ensure that the coronary ostia are not obstructed and that the stent posts of the replica end do not interfere with the aortic wall at the sinotubular junction. If satisfied with the fit of the replica end, implant this size of the bioprosthesis (Figure 8).
3	**Optional**-Determine if implanting a larger bioprosthesis 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 stent posts of the replica end do not interfere with the aortic wall at the sinotubular junction (Figure 8). If the larger size replica end fits comfortably above the patient's annulus, implant this size of the bioprosthesis. If the larger size replica end does not fit comfortably, implant the bioprosthesis size identified in the previous step. A suture technique resulting in supra-annular placement of the bioprosthesis, such as a horizontal mattress technique, should be employed.

12.5.2 Intra-Annular Sizing and Implantation

When an intra-annular technique is utilized, the entire bioprosthesis including the sewing ring is placed inside the annulus. Either the cylindrical or replica end of the model 1133 sizer can be used for intra-annular sizing.

For proper implantation of the bioprosthesis in the intra-annular position, 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 (Figures 10-12). A suture technique resulting in intra-annular placement of the bioprosthesis, such as an everting mattress technique, should be employed.

Step	Procedure
1	Suture the bioprosthesis in place using an appropriate suture technique that avoids the potential problems noted in this section.

- 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.
- 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 sewing 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 purse string 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.
- 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.

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

12.5.3 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:

Step	Procedure
1	Cut each of the three exposed sutures that are on the top of the holder utilizing a scalpel (Figure 13). **CAUTION: Avoid cutting or damaging the stent or delicate leaflet tissue when cutting the sutures.**
2	After 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	Remove the holder from the handle and discard the holder. If using the model 1111 handle, clean and sterilize the handle before each use (reference **12.3 Accessory Sterilization**).

12.6 Return of Explanted Bioprostheses

Edwards Lifesciences is extremely interested in obtaining recovered clinical specimens of Carpentier-Edwards PERIMOUNT Magna Ease aortic bioprostheses for analysis. A written report summarizing our findings will be provided upon completion of our evaluation. Please contact your local bioprosthesis specialist for return of recovered bioprostheses. The explanted bioprostheses should be placed into a suitable histological fixative such as10% formalin or 2% glutaraldehyde and returned to the company. Refrigeration is not necessary under these circumstances.

13.0 Patient Information

13.1 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.

13.2 Patient Manual

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

14.0 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 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.

15.0 References

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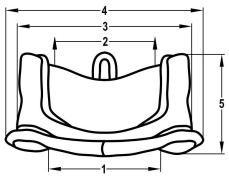
Table 1: Nominal Dimensions (mm)

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



Size	19 mm	21 mm	23 mm	25 mm	27 mm	29 mm
1. Inflow Orifice Diameter (mm)	17.0	19.0	21.0	23.0	25.0	27.0
2. Effective Orifice Diameter (mm)	15.0	16.0	17.5	19.0	20.5	22.5
3. Valve Housing External Diameter (mm)	19.0	21.0	23.0	25.0	27.0	29.0
4. External Sewing Ring Diameter (mm)	24.0	26.0	28.0	30.5	33.0	35.0
5. Total Profile Height (mm)	13	14	15	16	17	18

Note: For sizing, see Section 12.5 Device Implantation.

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

	Valve Size						
	19 mm	**21 mm**	**23 mm**	**25 mm**	**27 mm**	**29 mm**	**Total**
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, NYHA Functional Class, 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: Freedom from Complication Rates at 20 years (N = 267), Model 2700

Freedom from Complications at 20 Years	**Actual**	**Actuarial**	**Linearized (%/ptyr)**
Valve-Related Expirations	85.8 ± 2.5%	67.9 ± 6.6%	1.2
Thromboembolism/Thrombosis	82.4 ± 2.6%	68.2 ± 6.8%	1.7
Bleeding	94.0 ± 1.5%	91.7 ± 2.2%	0.4
Endocarditis/Sepsis	91.7 ± 1.7%	89.3 ± 2.4%	0.8
Explant due to SVD			
≥ 60	92.6 ± 2.0%	77.1 ± 7.2%	n.r.*
≥ 65	96.3 ± 1.6%	81.5 ± 9.6%	
≥ 70	96.0 ± 2.3%	69.9 ± 20.5%	

** Not relevant. SVD does not occur as a constant hazard function; consequently, linearized rates are not meaningful.*

Table 6: Summary of Valve-Related Adverse Events, Models 3000 and 3000TFX

	≤ 30 Days Post Operative		**> 30 Days Post Operative**	
Adverse Events	**3000TFX (N = 193) # of events (% of Pts)**	**3000/3000TFX (N = 253) # of events (% of Pts)**	**3000TFX (N = 193) # of events (% of Pts)**	**3000/3000TFX (N = 253) # of events (% of Pts)**
Valve-Related Thromboembolism	6 (3.1)	7 (2.8)	3 (2.0)	3 (1.4)
Non-Structural Valve Dysfunction (PVL)	3 (1.5)	4 (1.6)	3 (2.0)	3 (1.4)
Explant (NSVD)	2 (1.0)	2 (0.8)	0 (0.0)	0 (0.0)
Death (Cardiac Arrest, Bleeding Event, CVA)	1 (0.5)	1 (0.4)	3 (2.0)	3 (1.4)
Reoperation	1 (0.5)	1 (0.4)	1 (0.7)	1 (0.5)
Hemolysis	1 (0.5)	1 (0.4)	3 (2.0)	3 (1.4)
AC related Bleeding	0 (0.0)	0 (0.0)	2 (1.4)	2 (1.0)
Endocarditis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Structural Valve Deterioration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Valve Thrombosis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Other (Tear In Aorta)	1 (0.5)	1 (0.4)	0 (0.0)	0 (0.0)

Table 7: Hemodynamic Variables at 1-Year Follow-Up Echo Assessment, Models 3000 and 3000TFX

Valve Type	Variable	19 mm Mean ± SD (N)	21 mm Mean ± SD (N)	23 mm Mean ± SD (N)	25 mm Mean ± SD (N)	27 mm Mean ± SD (N)	29 mm Mean ± SD (N)
3000TFX	Mean Systolic Gradient (mmHg)	16.7 ± 4.7 (10)	15.8 ± 4.4 (18)	11.3 ± 3.7 (45)	11.1 ± 4.1 (37)	9.4 ± 4.3 (12)	9.0 ± 0.0 (2)
	Ejection Fraction (%)	65.8 ± 10.4 (10)	62.7 ± 9.4 (19)	60.6 ± 11.3 (48)	61.4 ± 11.2 (38)	59.5 ± 10.7 (12)	55.0 ± 14.1 (2)
	Aortic EOA (cm^2)	1.2 ± 0.4 (10)	1.5 ± 0.4 (18)	1.8 ± 0.6 (44)	1.8 ± 0.5 (36)	2.1 ± 0.6 (12)	2.1 ± 0.1 (2)
3000/ 3000TFX	Mean Systolic Gradient (mmHg)	16.7 ± 4.2 (16)	13.8 ± 4.8 (34)	11.7 ± 4.7 (56)	11.0 ± 3.8 (47)	9.5 ± 4.1 (14)	9.0 ± 0.0 (2)
	Ejection Fraction (%)	62.1 ± 15.1 (16)	58.6 ± 11.6 (34)	60.2 ± 11.2 (59)	60.2 ± 11.5 (47)	58.5 ± 10.5 (14)	55.0 ± 14.1 (2)
	Aortic EOA (cm^2)	1.3 ± 0.5 (16)	1.5 ± 0.4 (32)	1.8 ± 0.6 (55)	1.8 ± 0.6 (46)	2.1 ± 0.6 (14)	2.1 ± 0.1 (2)

Table 8: NYHA Functional Class: Change From Baseline To 1-Year Visit, Models 3000 and 3000TFX

		---Baseline---				
Valve Type	**Follow-Up NYHA Class**	**Class I**	**Class II**	**Class III**	**Class IV**	**N/A**
3000TFX/ N = 193	**Class I**	10	33	51	10	3
	Class II	2	8	13	2	1
	Class III	-	-	3	-	-
	Class IV	-	-	-	1	-
	Expiration	-	3	16	1	-
	Explant	-	-	3	-	-
	N/A	2	6	21	4	-
3000/3000TFX N = 253	**Class I**	12	40	71	11	3
	Class II	2	14	29	3	1
	Class III	-	-	3	-	-
	Class IV	-	-	1	1	-
	Expiration	-	3	19	2	-
	Explant	-	-	3	-	-
	N/A	2	7	22	4	-

Table 9: NYHA Functional Class: Change From Baseline To 1-Year Visit

Valve Type	Improve N (%)	Same N (%)	Worse N (%)	N/A N (%)
3000TFX (N = 193)	109 (56.5)	22 (11.4)	2 (1.0)	60 (31.1)
3000/3000TFX (N = 253)	154 (60.9)	30 (11.9)	3 (1.2)	66 (26.1)

Figures

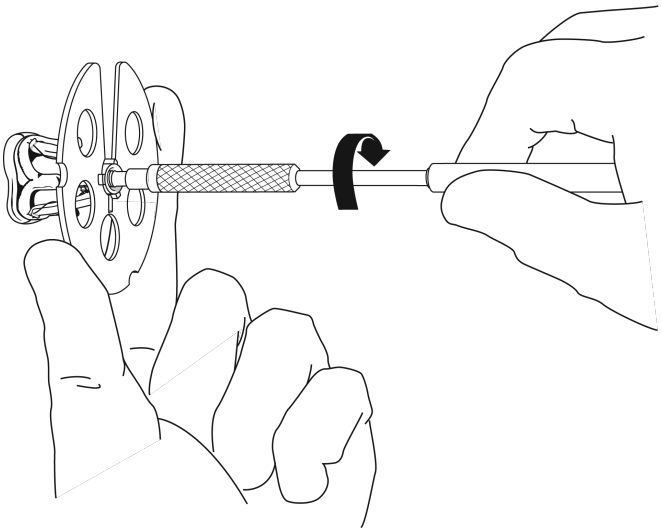


Figure 1: Handle Attachment

Figure 2: Clip Removal

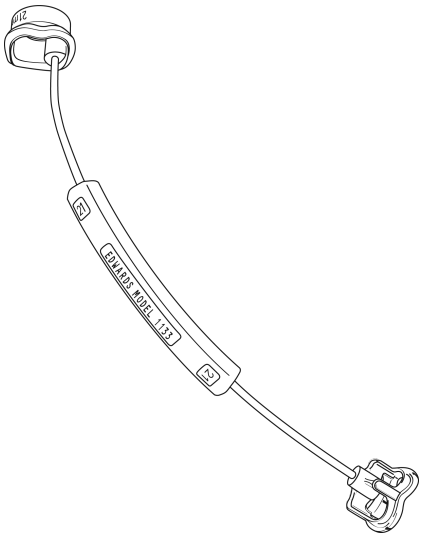


Figure 3: Aortic Sizer

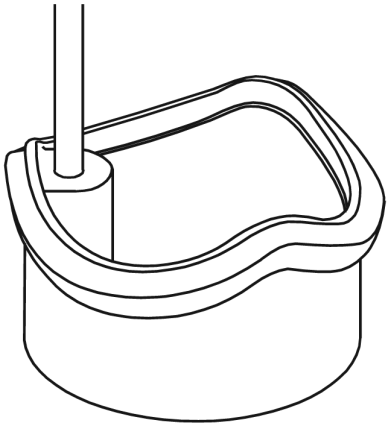


Figure 4: Cylindrical Sizer

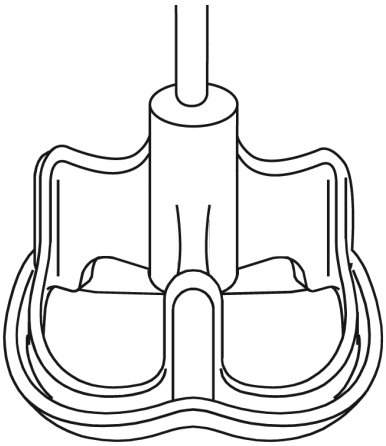


Figure 5: Replica Sizer

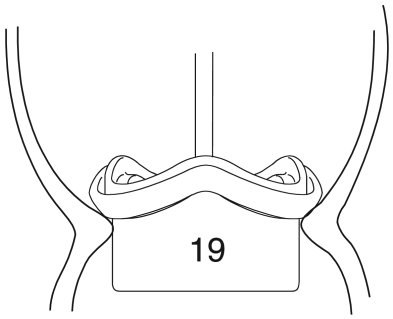


Figure 6: Supra-Annular Measurement

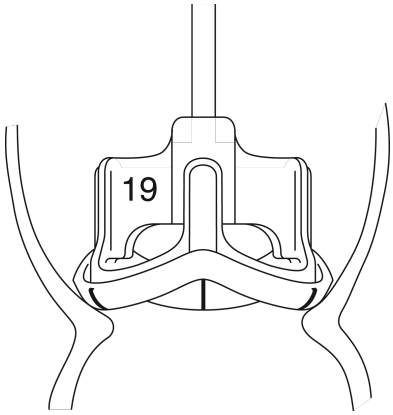


Figure 7: Supra-Annular Measurement

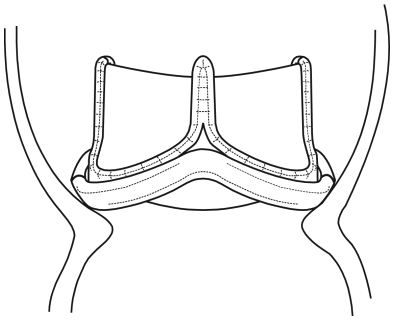


Figure 8: Supra-Annular Placement

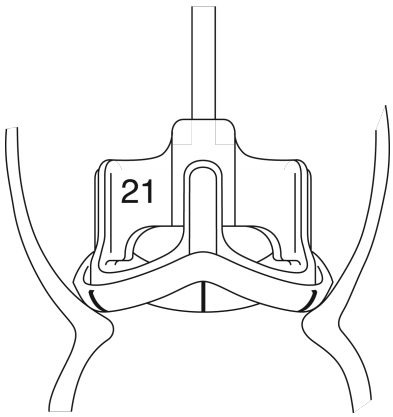


Figure 9: Supra-Annular Measurement

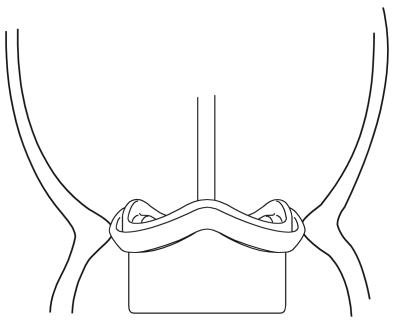


Figure 10: Intra-Annular Measurement

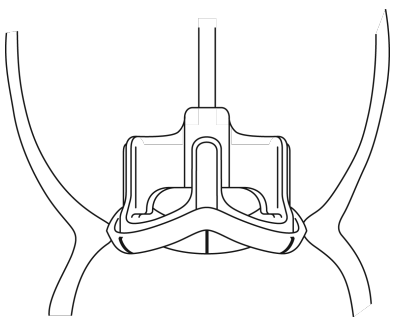


Figure 11: Intra-Annular Measurement

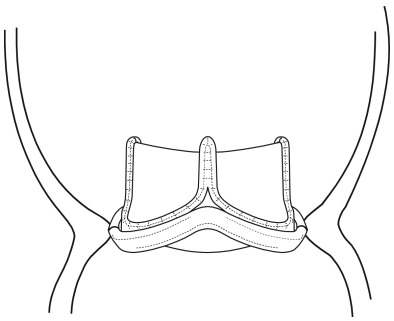


Figure 12: Intra-Annular Placement

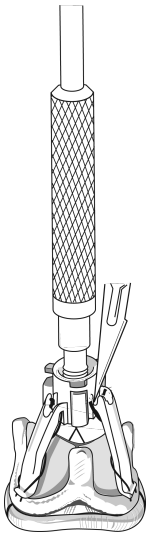


Figure 13: Aortic

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