

# Carpentier-Edwards PERIMOUNT RSR Pericardial Aortic Bioprosthesis



Model 2800TFX

## Bioengineered PERIMOUNT valve technology

Since its introduction in 1981, the PERIMOUNT valve has proven its long-term performance, based on key elements designed to optimize hemodynamics and valve durability<sup>1-4</sup>:

- Three independent symmetrical pericardial leaflets are matched for thickness and elasticity for long-term endurance and full valve opening
- Leaflets are mounted under the flexible stent to transfer stress during the cardiac cycle from the tissue to the stent
- Flexible cobalt-chromium stent absorbs and distributes stress evenly to minimize fatigue areas

## Indications

The Carpentier-Edwards PERIMOUNT RSR (Reduced Sewing Ring) pericardial 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.

## Tissue Treatment\*

The PERIMOUNT valve is treated with the Carpentier-Edwards ThermoFix\* process, which confronts both major calcium binding sites: residual glutaraldehydes and phospholipids.

Progressive tissue calcification is indeed the main cause of failure of biological valves<sup>5</sup>. By removing potential calcium binding sites, tissue treatment has been shown to reduce the risk of structural valve deterioration (SVD)<sup>6</sup>.

## General Product Information

- **Storage Temperature:** 10°C to 25°C
- **Storage Solution:** Glutaraldehyde
- **Rinse Procedure:**  
500 ml (sterile physiological saline solution) x 60 seconds  
repeat once using new saline solution
- **MRI Safety Information:** A patient with the valve can be scanned safely, the following conditions: Static magnetic field of 3 tesla or less, spatial gradient field of less than 3000 gauss/cm and maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg in the normal operating mode for 15 minutes of MR scanning per sequence.



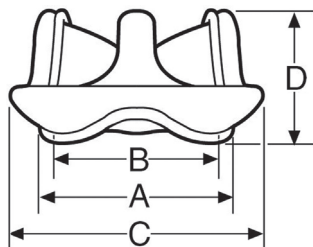
The PERIMOUNT bioprosthesis design has been in clinical use for more than 38 years

\* No clinical data are available which evaluate the long-term impact of the Edwards Lifesciences tissue treatments in patients.



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## Specifications



### Model 2800TFX

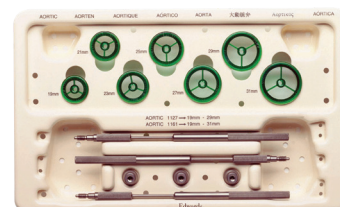
Size	19 mm	21 mm	23 mm	25 mm	27 mm	29 mm
A. Mounting Diameter (Annulus)	19	21	23	25	27	29
B. Internal Diameter (Stent I.D.)	18	20	22	24	26	28
C. External Sewing Ring Diameter	26	28	31	32	35	37
D. Total Profile Height	14	15	16	17	18	19

Significant dimensions in millimeters (nominal values)

## Sizers and Accessories

### Model 1161SET

Complete sizer set



### Model 1111

Reusable handle



### Model 1126

Single-use handle (extended length)



## References

1. Aupart MR, Mirza A, Meurisse YA, et al. Perimount pericardial bioprosthesis for aortic calcified stenosis: 18-year experience with 1133 patients. *J Heart Valve Dis.* 2006;15(6):768-775.
2. Bergoënd E, Aupart MR, Mirza A, et al. 20 years' durability of Carpentier-Edwards Perimount stented pericardial aortic valve. In: Yankah CA, Weng Y, Hetzer R, eds. *Aortic Root Surgery The Biological Solution*. Berlin: Springer; 2010:441-451.
3. Jamieson WR, Germann E, Aupart MR, et al. 15-year comparison of supra-annular porcine and PERIMOUNT aortic bioprostheses. *Asian Cardiovasc Thorac Ann.* 2006;14(3):200-205.
4. Wagner IM, et al. Influence of completely supra-annular placement of bioprostheses on exercise hemodynamics in patients with a small aortic annulus. *J Thorac Cardiovasc Surg* 2007;133(5):1234-41.
5. Schoen FJ et al Calcification of Tissue Heart Valve Substitutes: Progress Toward Understanding and Prevention *Ann Thorac Surg* 2005;79:1072- 8.
6. Flameng et al. Antimineralization treatment and patient-prosthesis mismatch are major determinants of the onset and incidence of structural valve degeneration in bioprosthetic heart valves. *J Thorac Cardiovasc Surg* 2014 Apr;147(4):1219-24

**For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.**

Edwards Lifesciences devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

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