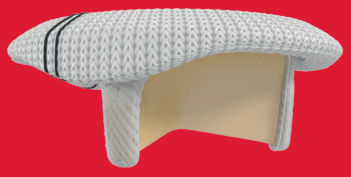
Mitral

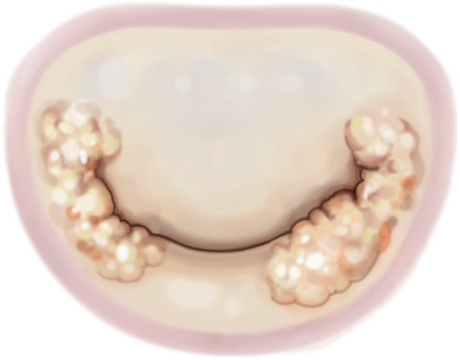


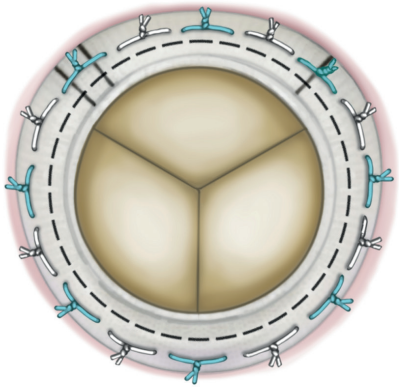
Carpentier-Edwards PERIMOUNT

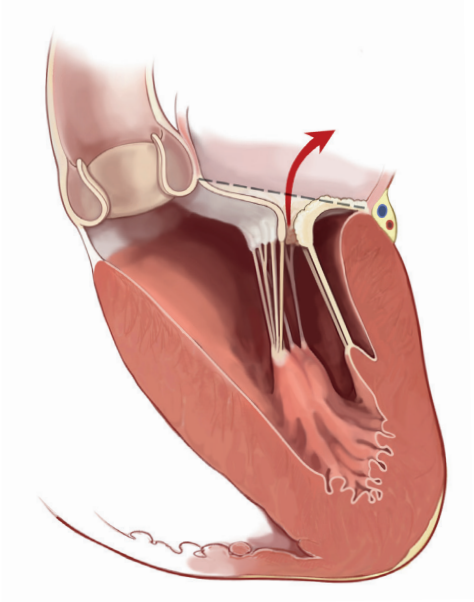
Magna Mitral Ease

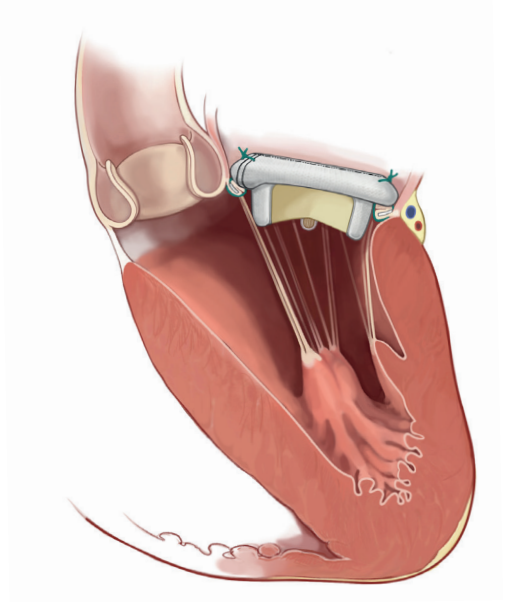
Bioprosthesis

When Your patient needs an ultra low-profile valve with decreased ventricular projection by up to 40% *









Procedure illustration adapted from Carpentier, et al. Elsevier, 2010.

* As compared to the Carpentier-Edwards PERIMOUNT Plus Mitral Pericardial Bioprosthesis

Edwards

Carpentier-Edwards PERIMOUNT Magna Mitral Ease Bioprosthesis

Process

ThermaFix process anticalcification technology**

- Confronts both major calcium binding sites: residual glutaraldehydes and phospholipids

Tissue

Built on the Carpentier-Edwards PERIMOUNT valve design platform

Three individual matched bovine leaflets

Design

Mitral-specific supra-annular design

- Wide saddle shaped cuff that mimics mitral anatomy
- LVOT reference markers to ensure optimal orientation
- Unique suture guide to simplify suture placement
- Single cut handle release
- Tricentrix holder for ease of implantation

Ultra-low profile

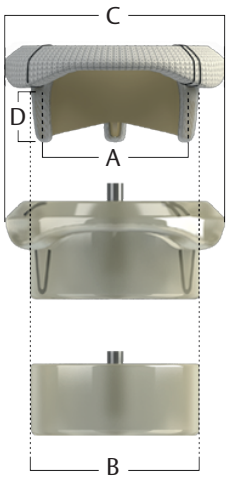
- Reduced ventricular projection by up to 40% *
- 7.0 mm stent post protrusion into left ventricle on size 25 mm valve

* As compared to the Carpentier-Edwards PERIMOUNT Plus Mitral Pericardial Bioprosthesis

** No clinical data are available which evaluate the long-term impact of the Carpentier-Edwards ThermaFix treatment in patients

Carpentier-Edwards PERIMOUNT Magna Mitral Ease Bioprosthesis

Model 7300TFX					
Available in odd sizes 25 mm – 33 mm	**Size 25**	**Size 27**	**Size 29**	**Size 31**	**Size 33**
A. Stent Diameter (Wireform)	25	27	29	31	31
B. Tissue Annulus Diameter	28	29.5	31.5	33.5	33.5
C. External Sewing Ring Diameter	36	38	40	42	44
D. Anterior Effective Profile	7	7.5	8	8.5	8.5



Sizers	Handle Options
Barrel Sizer Accessory Set SET1173B	Flexible, Reusable Handle 1173
Replica Sizer Accessory Set SET1173R	Reusable Handle 1111
	Flexible, Reusable Mitral Handle 1117
	Longer, Single Use Handle 1126

For more information on product specifications, please visit www.edwards.com/gb

Brief Summary: Carpentier-Edwards PERIMOUNT Magna Mitral Ease Bioprosthesis

Indications: For use in patients whose mitral valvular disease warrants replacement of their natural or previously placed prosthetic valve and when the mitral valve cannot be repaired. **Contraindications:** Do not use if surgeon believes such would be contrary to the patient's best interests. **Complications and Side Effects:** Stenosis, regurgitation, endocarditis, hemolysis, thromboembolism, valve thrombosis, nonstructural dysfunction, structural valve deterioration, anemia, arrhythmia, hemorrhage, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, angina, ventricular perforation by stent posts (mitral valve only), any of which could lead to reoperation, explantation, permanent disability and death. **Warnings:** Alternative therapies should be considered in the presence of conditions affecting calcium metabolism or when calcium containing chronic drug therapies are used, including children, adolescents, young adults and patients on a high calcium diet or maintenance hemodialysis. Should be used with caution in the presence of severe systemic hypertension or when anticipated patient longevity is longer than the known longevity of the prosthesis.

These physicians receive royalty payments in connection with these devices and are paid consultants of Edwards Lifesciences: David Adams, M.D.; Ottavio Alfieri, M.D.; Alain Carpentier, M.D. Ph.D.; Delos Cosgrove, M.D.; Ruggero De Paulis, M.D.; Francesco Maisano, M.D.; Patrick McCarthy, M.D. and Alberto Redaelli, M.D.

For professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

Edwards 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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