

CARPENTIER-EDWARDS PERIMOUNT
MAGNA MITRAL EASE
PERICARDIAL BIOPROSTHESIS

WHEN THE MOMENT MATTERS:
MAKE THE CHOICE YOU
WOULD MAKE FOR YOURSELF



CARPENTIER-EDWARDS PERIMOUNT
MAGNA MITRAL EASE
PERICARDIAL BIOPROSTHESIS

With the Magna Mitral Ease valve, you can choose with confidence, knowing you are getting a valve from Edwards Lifesciences, the worldwide leader in heart valve therapy.

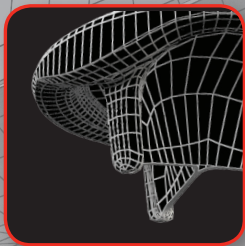
Built upon the unique and proven PERIMOUNT valve design, the Magna Mitral Ease valve gives you and your patients:

- **Ultra-low** profile, with reduced ventricular projection by up to 40%*
- Exceptional **Long-Term Durability**
- **Ease of Implant**

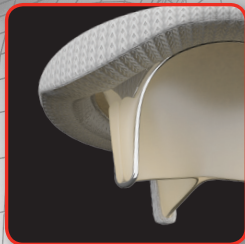
*As compared to the Carpentier-Edwards PERIMOUNT Theon mitral valve

It all starts with the
Proven PERIMOUNT Design

The Magna Mitral Ease valve is built upon the proven, time-tested PERIMOUNT valve design, with unique design elements including:



- **Mathematically modeled, bioengineered design**
Intended to optimize **implantability**, **hemodynamics** and **long-term durability**



- **Flexible cobalt-chromium alloy stent**
Absorbs energy to reduce leaflet stress



- **Three independent bovine pericardial leaflets**
Matched for thickness and elasticity to optimize stress distribution

ULTRA-LOW PROFILE, WITH REDUCED VENTRICULAR PROJECTION BY UP TO 40%*

- Supra-annular position and asymmetrical design, help to reduce ventricular projection†



*†As compared to the Carpentier-Edwards PERIMOUNT Theon mitral valve

EASE OF IMPLANT

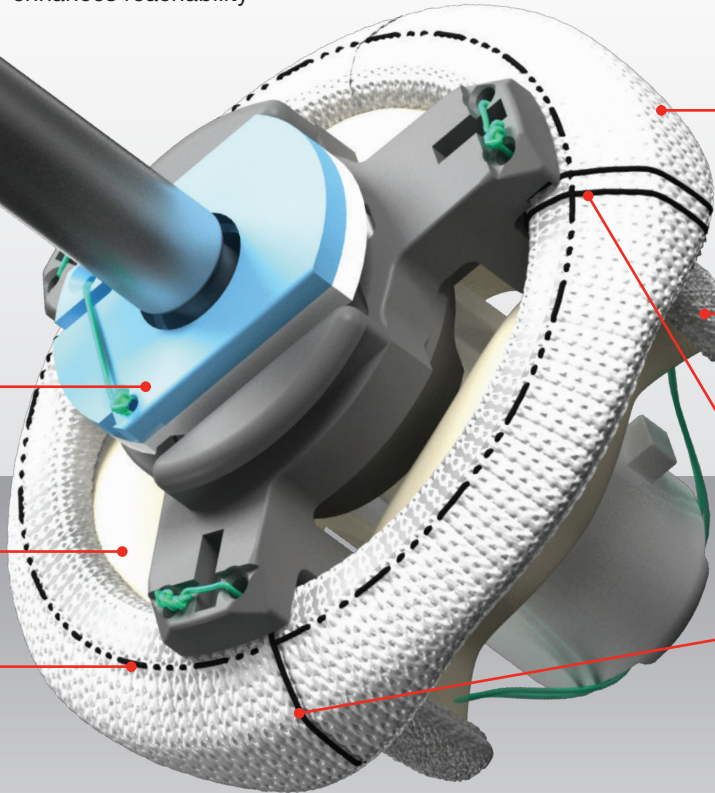
- Wide, contoured cuff with unique anterior saddle and lateral contour to mimic the shape of the native mitral anatomy

Long, multi-bend handle
enhances reachability

Single-cut handle
for quick release

ThermaFix process**

Unique suture guide
simplifies suture placement



Wide, saddle-shaped cuff
mimics annular anatomy

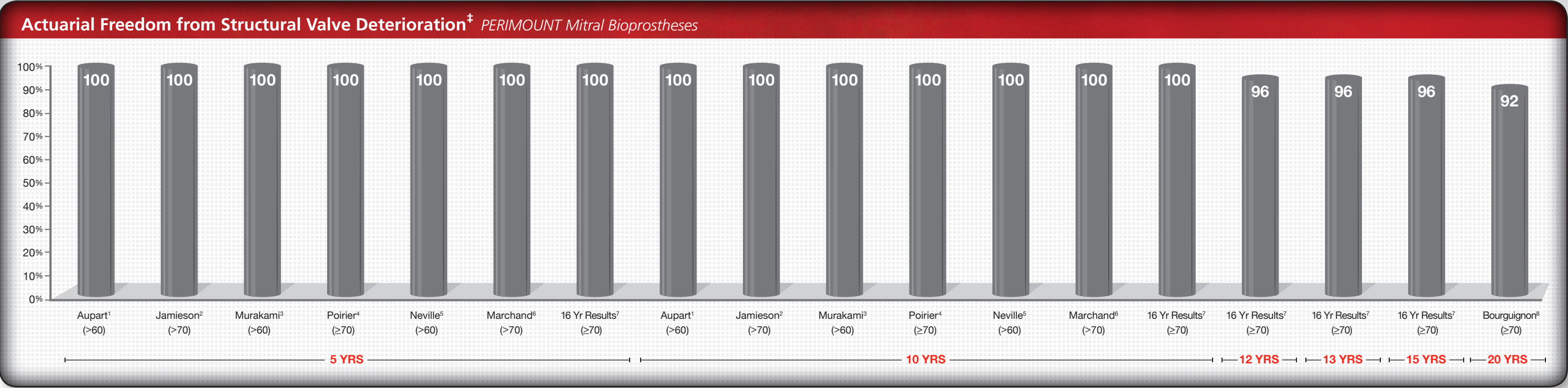
Retractable stent posts
to minimize the potential for suture entrapment during implantation

LVOT reference markers
help ensure optimal orientation

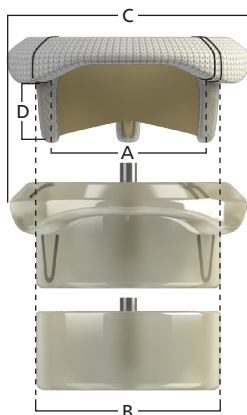
**No clinical data are available that evaluate the long-term impact of the Carpentier-Edwards ThermaFix treatment in patients.

EXCEPTIONAL LONG-TERM DURABILITY

- Built on the proven performance of the PERIMOUNT valve design, with published clinical durability of up to 20 years

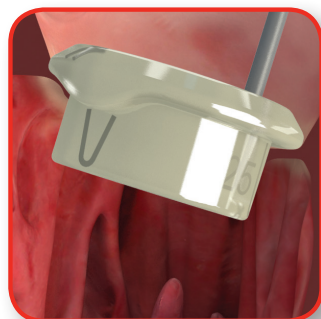
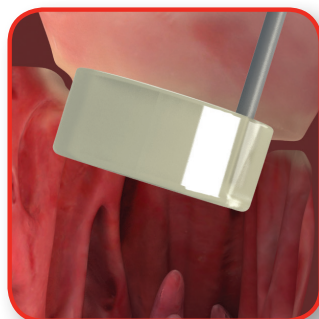


[‡]Patients and results are a subset of each study. Reporting methods vary among literature sources. See references for definitions.



Model 7300TFX Nominal Specifications (mm)

Size	25 mm	27 mm	29 mm	31 mm	33 mm
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



Pre-attached barrel and replica sizers facilitate valve sizing

Accessories

Barrel Sizer Accessory Set	SET1173B
Replica Sizer Accessory Set	SET1173R
Flexible, reusable handle	1173



Flexible handle with valve attached

References

1. Aupart, MR, et al. Carpentier-Edwards pericardial valves in the mitral position: ten-year follow-up. J Thorac Cardiovasc Surg. 1997 Mar;113(3):492-8. (Freedom from structural deterioration; n = 150; mean age = 62.9 ± 11.9 yrs)
2. Jamieson, WRE, et al. Structural Valve Deterioration in Mitral Replacement Surgery: Comparison of Carpentier-Edwards Supra-Annular Porcine and PERIMOUNT Pericardial Bioprostheses. J Thorac Cardiovasc Surg. 1999 Aug;118:297-305. (Freedom from explant due to structural valve deterioration; n = 429; mean age = 60.7 ± 11.7 yrs)
3. Murakami, T, et al. Aortic and mitral valve replacement with the Carpentier-Edwards pericardial bioprosthesis: 10-year results. J Heart Valve Dis. 1996 Jan;5(1):45-9. (Freedom from structural deterioration; n = 57, mean age = 55.1 ± 13.2 yrs)
4. Poirier, NC, et al. 15-year experience with the Carpentier-Edwards pericardial bioprosthesis. Ann Thorac Surg. 1998;66:S57-61. (Freedom from structural deterioration; n = 214; mean age = 65 ± 23 yrs)
5. Neville, PH, et al. Carpentier-Edwards pericardial bioprosthesis in aortic or mitral position: a 12-year experience. Ann Thorac Surg. 1998;66(6 Suppl):S143-7. (Freedom from structural deterioration; n = 182; mean age = 63.9 ± 11.5 years)
6. Marchand, MA, et al. Fifteen-year experience with the mitral Carpentier-Edwards PERIMOUNT pericardial bioprosthesis. Ann Thorac Surg. 2001 May;71(5 Suppl):S236-9. (Freedom from structural valve deterioration; n = 435; mean age = 60.7 ± 11.6 yrs)
7. Carpentier-Edwards PERIMOUNT pericardial bioprosthesis 16-year results. Data on file at Edwards Lifesciences, 2003. (Freedom from explant due to structural valve deterioration; n = 404 mean age = 60.7 ± 11.6 yrs)
8. Bourguignon, T, et al. Very late outcomes for mitral valve replacement with the Carpentier-Edwards pericardial bioprosthesis: 25 year follow-up of 450 implantations. J Thorac Cardiovasc Surg. 2014 Nov;148:2004-11. (Freedom from explant due to structural valve deterioration; n = 404; mean age = 68.0 ± 10.4 yrs)

Brief Summary: Mitral Bioprostheses

Indications: For use in patients whose mitral valvular disease warrants replacement of their natural or previously placed prosthetic valve and when the valve cannot be repaired. **Contraindications:** Do not use if surgeon believes it 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, 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.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. See the Instructions for Use for a full description of prescribing information.

Edwards, Edwards Lifesciences, the stylized E logo, Carpentier-Edwards, Magna, Magna Mitral Ease, PERIMOUNT, PERIMOUNT Magna, TheraFix and TFX are trademarks of Edwards Lifesciences Corporation. All other trademarks are the property of their respective owners.

© 2015 Edwards Lifesciences Corporation. All rights reserved. PP--US-0336 v1.0

Edwards Lifesciences | edwards.com

One Edwards Way | Irvine, California 92614 USA
Switzerland | Japan | China | Brazil | Australia | India

