

Mitral Valve



For

Mitral valve replacement

When

If patients need a mitral valve replacement, give them a RESILIA tissue valve designed for the mitral position

Why

RESILIA tissue* offers enhanced anti-calcification technology that will potentially allow the valve to last longer

RESILIA tissue

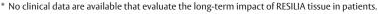
- Significant improvement of anti-calcification properties in test valves compared to control[†]
- Sustained hemodynamic performance[†]

Mitral-specific design

- Built to handle the pressure of the mitral position
- Atrialized cuff design reduces ventricular projection and minimizes risk of left ventricular outflow tract (LVOT) obstruction and left venticular (LV) wall injury

Proven valve platform

- Built on the proven performance of the Carpentier-Edwards PERIMOUNT valve design – a valve design with published clinical durability¹ of over 20 years
- Enhanced mitral implantability

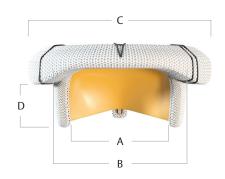


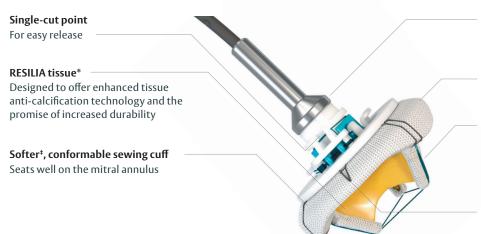




Model 11400M

Valve Size (mm)	25 mm	27 mm	29 mm	31 mm	33 mm
A. Stent Diameter (Wireform, mm)	25	27	29	31	31
B. Tissue Annular Diameter (mm)	27.5	29.5	31.5	33.5	33.5
C. External Sewing Ring Diameter (mm)	36	38	40	42	44
D. Effective Profile Anterior (mm)	7	7.5	8	8.5	8.5





Wide, short screw tip

Reduces number of turns to avoid cross threading of handle in the adaptor

Asymmetrical, saddle-shaped cuffMimics native mitral annulus

Foldable, nitinol stent posts

Minimizes the potential for suture entrapment and returns back to original position

Black "A" marking

Helps ensure optimal orientation with the anterior portion of the mitral annulus

Accessories

Model	Description
1173B	Individual barrel sizer 25–33 mm
SET1173B	Barrel sizer accessory set 25–33 mm
1173R	Individual replica sizers 25–33 mm
SET1173R	Replica sizer accessory set 25–33 mm

Handle

Reusable Handle 1140M Scan to learn more about the product



- * No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.
- ‡ Compared to Magna Mitral Ease valve (model 7300TFX)

References

- 1. 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;148:2004-11.
- 2. Flameng W, et al. A randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. J Thorac Cardiovasc Surg. 2015;149:340–5.

Important Safety Information: MITRIS RESILIA Mitral Valve

Indications: For use in replacement of native or prosthetic mitral heart valves. Contraindications: There are no known contraindications with the use of the MITRIS RESILIA mitral valve. Complications and Side Effects: Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, ventricular perforation by stent posts, any of which could lead to reoperation, explantation, permanent disability, and death.

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See Instructions for Use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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