

# Natural Saddle-Shaped Design Allows Durable, Full Remodeling.

The unique shape of the Rigid Saddle Ring is designed to mimic a healthy mitral annulus. Multiple studies show that the saddle shape contributes to the efficient distribution of stresses and tension over the leaflets and chordae tendineae.<sup>1–3</sup> This redistribution of stress may increase repair durability.<sup>2,3,5</sup>

### SHAPE MIMICS A HEALTHY ANNULUS

- Three-dimensional design restores the natural saddle shape.<sup>1-4</sup>
- Annular-height-to-commissural-width ratio of 15 percent mimics a healthy mitral annulus.<sup>2</sup>
- Complete titanium alloy core maintains anatomical shape and provides annular remodeling.

#### **CLINICAL BENEFITS**

- Saddle shape contributes to efficient distribution of leaflet stress and chordal tension. 1-3
- Redistribution of leaflet stress and chordal tension through saddle-shape remodeling may increase repair durability.<sup>2,3,5</sup>
- Polyester double-velour EZ Suture<sup>™</sup> Cuff may encourage tissue in-growth.<sup>6,7</sup>

#### PROPRIETARY FEATURES EASE IMPLANTATION

- EZ Suture Cuff is supported by a unique triangular core for a larger suture target.
- Clear, well-marked holder is designed to increase visibility during implant.
- Secure ergonomic handle quickly attaches and detaches to save time during implant.



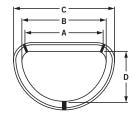
## **Ordering Information**

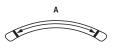
#### Rigid Saddle Ring

Model Number	Ring Size (mm)	Commissure Dimension (A) (mm)	Inside Dimension (B) (mm)	Outside Dimension (C) (mm)	A-P Dimension (D) (mm)	Internal 2-D Orifice Area (mm²)
RSAR-24	24	24	22	30	13.6	227
RSAR-26	26	26	24	32	15.1	276
RSAR-28	28	28	26	34	16.2	331
RSAR-30	30	30	28	36	17.9	387
RSAR-32	32	32	30	38	19.2	450
RSAR-34	34	34	32	40	20.6	511

#### Accessories

Model Number	Contents			
RSAR-507A	RSAR Sizer Set Complete			
	One (1) malleable holder handle			
	One (1) extension handle			
	Six (6) sizers (24, 26, 28, 30, 32, 34)			
	One (1) autoclavable tray for storage of components			
	One (1) autoclavable tray cover			
HH-05	Replacement Holder Handle			
EX-05	Replacement Extension Handle			





## Specifications

#### Rigid Saddle Ring Specifications

Fabric: Polyester Double Velour Core: Titanium

#### Sizer Specifications

Handle: Polyphenylsulfone Shaft: Nitinol Polysulfone

- 1. Jimenez JH, Soerensen DD, He Z, et al. Effects of a saddle shaped annulus on mitral valve function and chordal force distribution: an in vitro study. Ann Biomed Eng. 2003;31(10):1171-81.
- 2. Salgo IS, Gorman JH 3rd, Gorman RC, et al. Effect of annular shape on leaflet curvature in reducing mitral leaflet stress. Circulation. 2002;106(6):711-7
- 3. Jimenez JH, Liou SW, Padala M, et al. A saddle-shaped annulus reduces systolic strain on the central region of the mitral valve anterior leaflet. J Thorac Cardiovasc Surg. 2007;134(6):1562-8.

  4. Flachskampf FA, Chandra S, Gaddipatti A, et al. Analysis of shape and motion of the mitral annulus in subjects with and without cardiomyopathy by echocardiographic 3-dimensional
- reconstruction. J Am Soc Echocardiogr. 2000;13(4):277-87.
- 5. Gorman JH 3rd, Jackson BM, Enomoto Y, et al. The effect of regional ischemia on mitral valve annular saddle shape. Ann Thorac Surg. 2004;77(2):544-8.
- 6. Haverich A, Maatz W, Stegmann T, et al. Experimental and clinical experiences with double-velour woven Dacron prostheses. *Thorac Cardiovasc Surg.* 1986;34(1):52-3. 7. Sato O, Tada Y, Takagi A. The biologic fate of Dacron double velour vascular prostheses. *Jpn J Surg.* 1989;19(3):301-11.

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Caution: Federal Law restricts this device to sale by or on the order of a physician or properly licensed practitioner. Please see the physician's manual for a full description of indications, contraindications, side effects, precautions, warnings, and instructions for use.

Brief Summary: Please review the Instructions for Use prior to using this device for a complete listing of indications, contraindications, precautions, potential adverse events, and directions for use.



