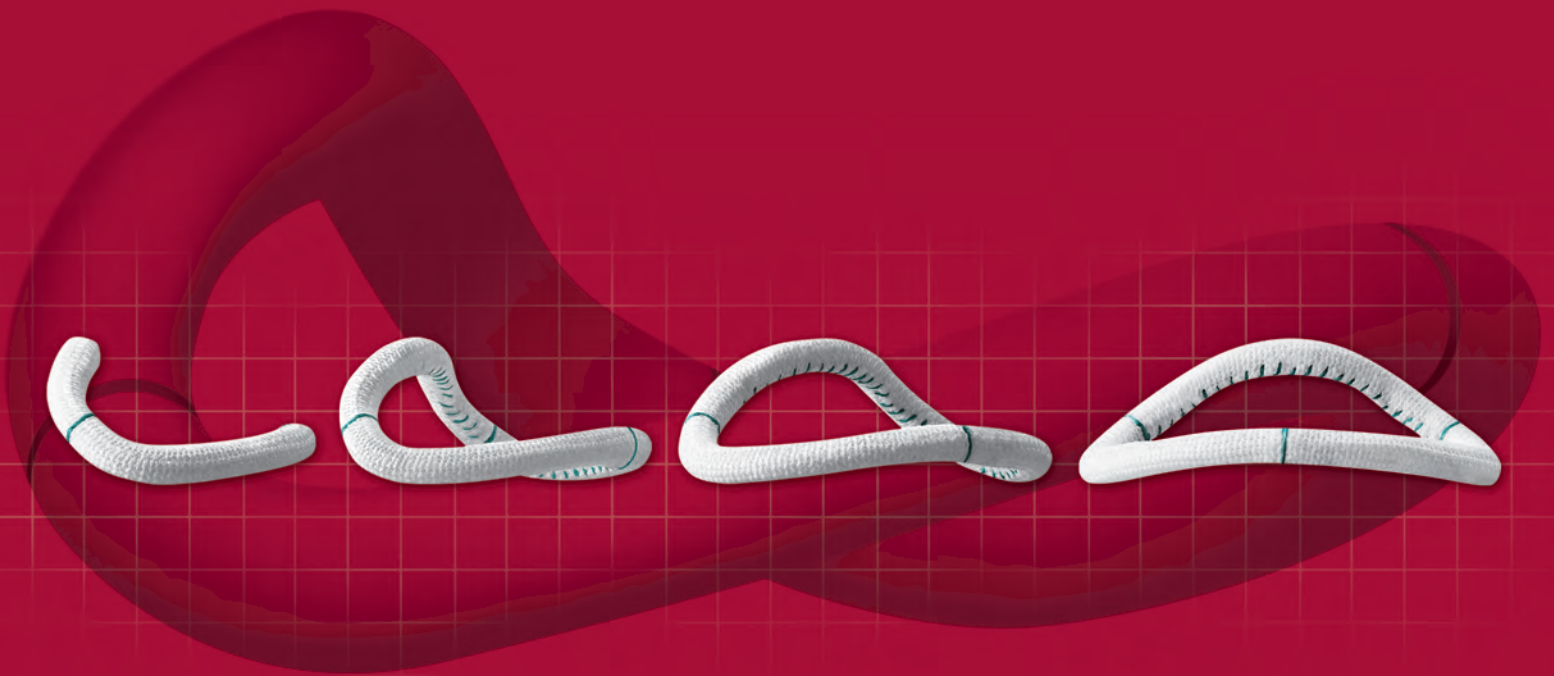


PROFILE 3D™

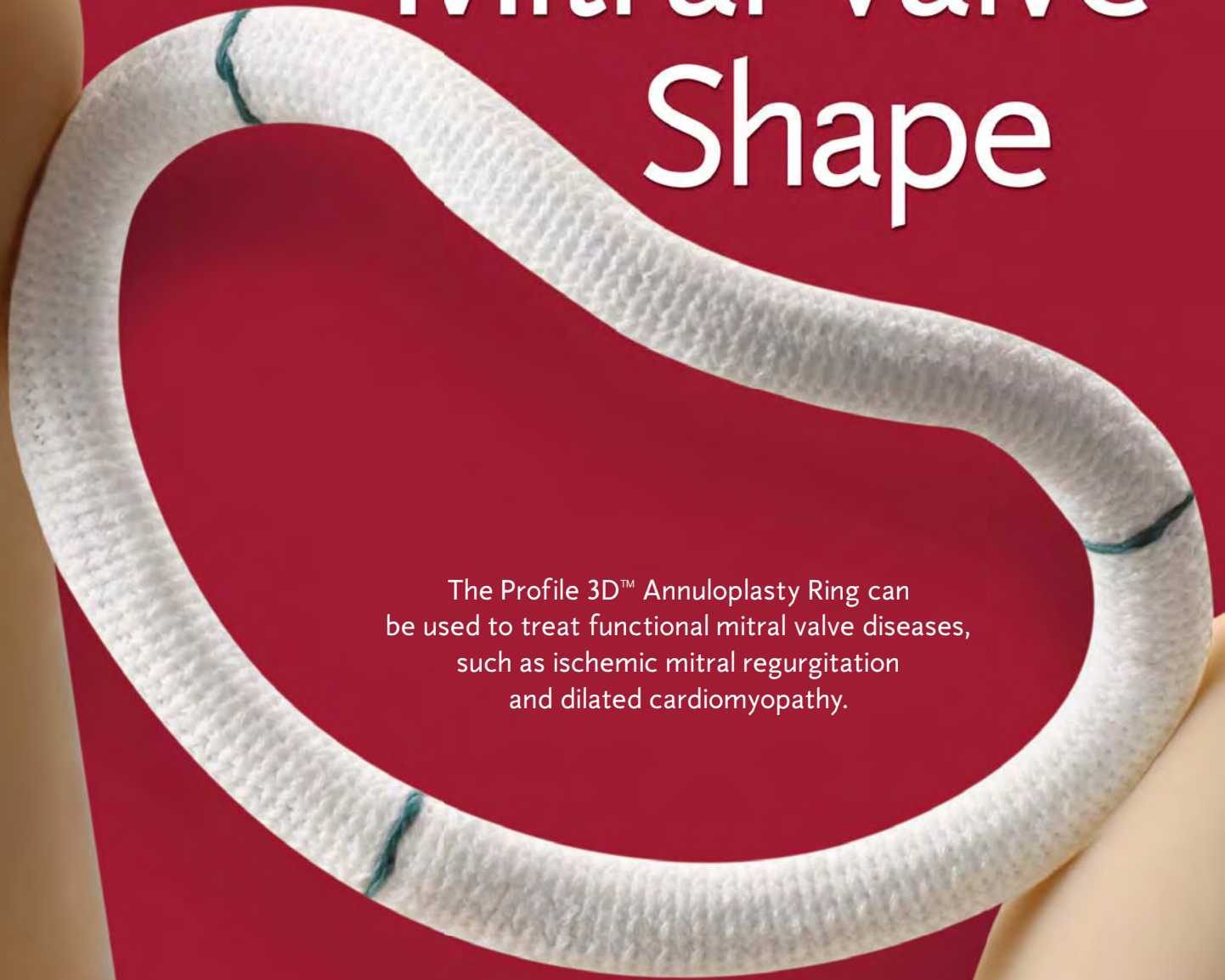
Annuloplasty System



Natural Dimensions for Mitral Valve Repair

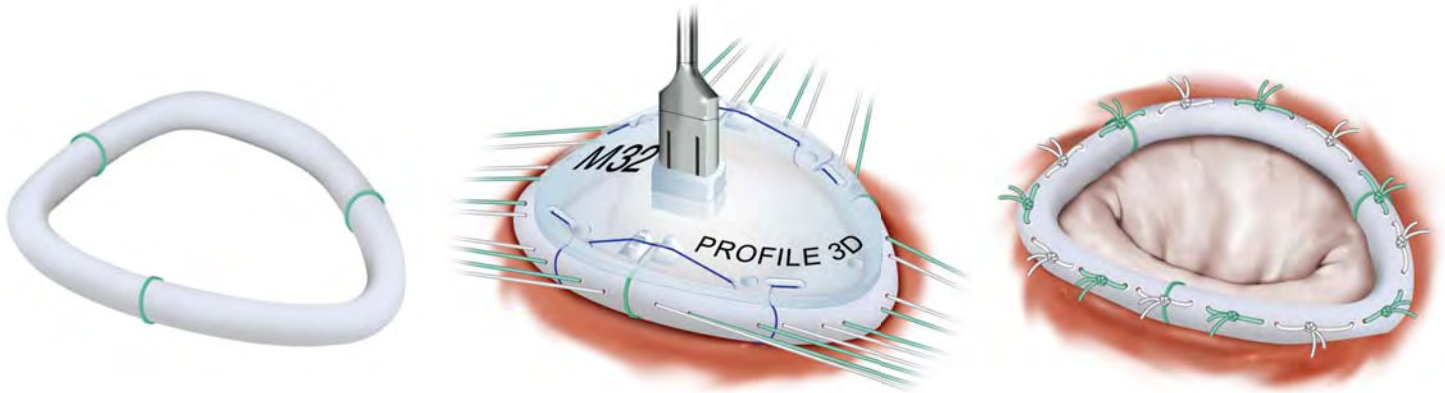
A Fully Rigid Remodeling Ring with a Physiologic Mitral Valve Shape

The Profile 3D™ Annuloplasty Ring can be used to treat functional mitral valve diseases, such as ischemic mitral regurgitation and dilated cardiomyopathy.



A Natural Design for Remodeling

In accordance with published clinical studies reported by the Gorman Cardiovascular Research Group, Glenolden Research Laboratory at the University of Pennsylvania,¹ Medtronic CardioVascular is pleased to introduce the new Profile 3D™ Annuloplasty System.² Based on the annular geometry of normal human mitral annuli, the saddle-shaped ring may reduce leaflet stress and increase mitral valve durability.^{1,2}



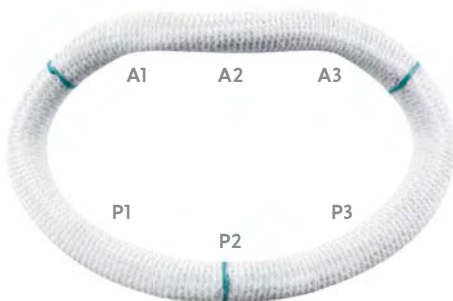
Saddle-Shape Design and Durability

Leaflet stress can be related to saddle height, which could affect long-term durability of mitral valve annuloplasty repair. Studies have found that the asymmetric saddle shape with an annular height to commissural width ratio (AHCWR) of 15-25% has the minimal peak leaflet stress.¹



The Mitral Valve has a Saddle Shape The mitral annulus is a dynamic, saddle-shaped structure with a maximum height of the saddle in the middle of the annulus's anterior part and another rise along the posterior leaflet.³

3-Dimensional Profile 3D™ Ring "...a saddle-shaped annuloplasty ring may increase mitral valve repair durability by reducing leaflet and chordal strain."¹

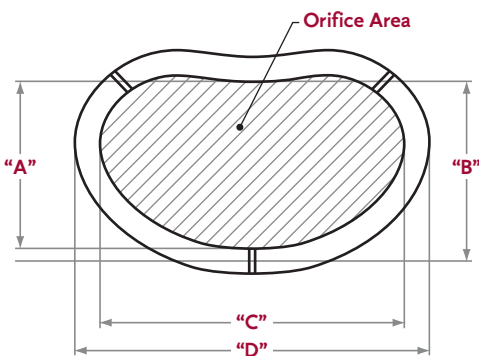


2-Dimensional Rigid Rings When implanted, rigid and semi-rigid devices only restore the annular geometry in two dimensions. The annulus height is obliterated, diminishing leaflet curvature and potentially placing increased stress and subsequent strain on valve repair.⁴

"...data strongly suggest that nature conserves the saddle-shaped annulus for a mechanical benefit."¹

Profile 3D™ Annuloplasty Ring Specifications and Ordering information

Order Number	Ring Description	A (mm)	B (mm)	C (mm)	D (mm)	Orifice Area
680R24	Profile 3D™ Annuloplasty Ring, Model 680R, 24 mm	13.4	15.0	24.2	30.5	278 mm ²
680R26	Profile 3D™ Annuloplasty Ring, Model 680R, 26 mm	14.5	16.1	26.2	32.5	325 mm ²
680R28	Profile 3D™ Annuloplasty Ring, Model 680R, 28 mm	15.6	17.2	28.2	34.5	376 mm ²
680R30	Profile 3D™ Annuloplasty Ring, Model 680R, 30 mm	16.7	18.3	30.2	36.5	430 mm ²
680R32	Profile 3D™ Annuloplasty Ring, Model 680R, 32 mm	17.8	19.4	32.2	38.5	489 mm ²
680R34	Profile 3D™ Annuloplasty Ring, Model 680R, 34 mm	18.9	20.5	34.2	40.5	550 mm ²
680R36	Profile 3D™ Annuloplasty Ring, Model 680R, 36 mm	19.8	21.4	36.2	42.5	612 mm ²
680R38	Profile 3D™ Annuloplasty Ring, Model 680R, 38 mm	20.9	22.5	38.2	44.5	683 mm ²
680R40	Profile 3D™ Annuloplasty Ring, Model 680R, 40 mm	22.0	23.6	40.2	46.5	756 mm ²



Order Number	Components and Accessories
7680S	Profile 3D™ Sizer Set (9 Profile 3D™ sizers, 24 - 40 mm)
7686	Annuloplasty Handle (216 mm length)
7686XL	Annuloplasty Handle (373 mm length)
T7680	Profile 3D™ Accessory Tray

References

- Salgo I, Gorman J, Gorman R, et al. Effect of annular shape on leaflet curvature in reducing mitral leaflet stress. *Circulation*. 2002;106:711-7.
- Published U.S. Patent Application Nos. 2005-0021135 A1 and 2006-0025856 A1.
- Fedak P, McCarthy P, Bonow R. Evolving concepts and technologies in mitral valve repair. *Circulation*. 2008;117:963-74.
- Gorman J, Jackson B, Enomoto Y, Gorman R. The effect of regional ischemia on mitral valve annular saddle shape. *Ann Thorac Surg* 2004;77:544-8.

Profile 3D™ Annuloplasty System

Indications: This device is indicated for the reconstruction and/or remodeling of pathological mitral valves. Valvular insufficiency and/or stenosis may be corrected by appropriate repair and annular remodeling.
Contraindications: Heavily calcified valves, valvular retraction with severely reduced mobility, active bacterial endocarditis. **Warnings/Precautions/Adverse Events:** Only physicians who have received proper training in valve repair should use this device. Adverse events can include: thromboembolic events, dehiscence, hemolysis, stenosis, residual incompetence, heart block, endocarditis, systolic anterior motion, left ventricular outflow tract obstruction, anticoagulant-related bleeding or hemorrhage.

For additional information please refer to the Instructions for Use provided with the product or contact your local Medtronic representative.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Profile 3D is a trademark of Medtronic, Inc.

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