

Medtronic

Accommodate anterior motion

SimuForm™ Annuloplasty Ring



Hybrid shape

The SimuForm ring provides semi-rigid posterior remodeling while offering a flexible anterior portion to accommodate motion.

The mitral valve annulus changes shape in the cardiac cycle – so does the SimuForm ring. With this unique design, the SimuForm platform has been reported to provide excellent functional results for mitral valve repair and effectively reduce the risk for systolic anterior motion (SAM) at midterm follow-up.¹

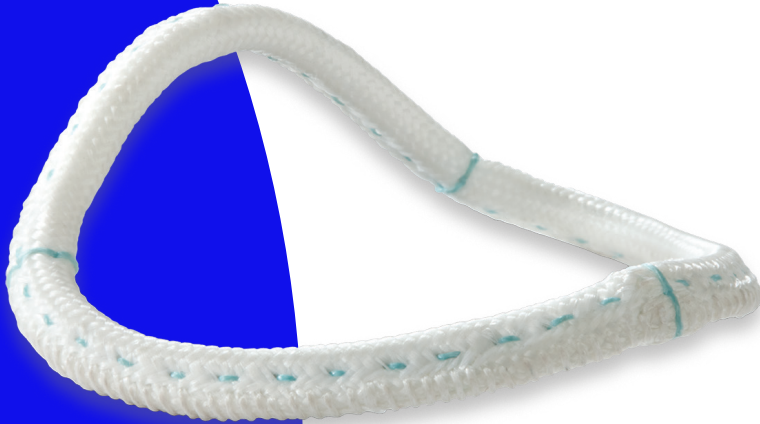
Key risks of mitral valve repair include recurrent regurgitation, stenosis, and ring dehiscence.

Elevated saddle shape in systole

- Flexible anterior portion which accommodates natural motion
- The saddle has been shown to increase leaflet coaptation and curvature,²⁻⁴ reduce annular forces,^{4,5} and reduce leaflet and chordal stresses⁵⁻⁷

Planar "O" shape in diastole

- SimuForm rings are not fixed into a saddle shape – they flatten to an "O" shape to accommodate diastolic filling dynamics.



Designed for excellent results

Results from a single-center, retrospective analysis show that the SimuForm platform¹:



Demonstrates excellent survival rates – 99.7% ± 0.2% at one year and 90.8% ± 4.6% at five years



Shows high repair success rate with very low rates of reoperation at midterm follow-up with conventional and minimally invasive access

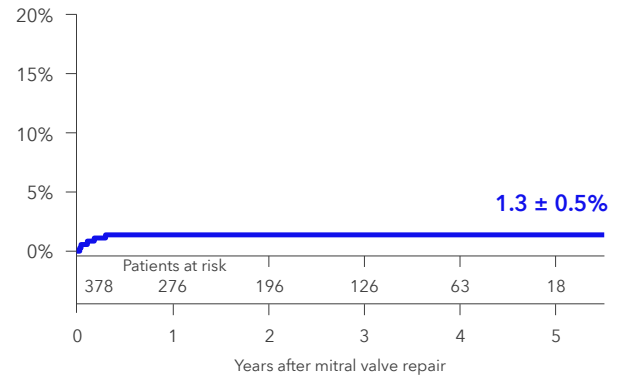


Effectively reduces the risk of recurrent mitral valve regurgitation

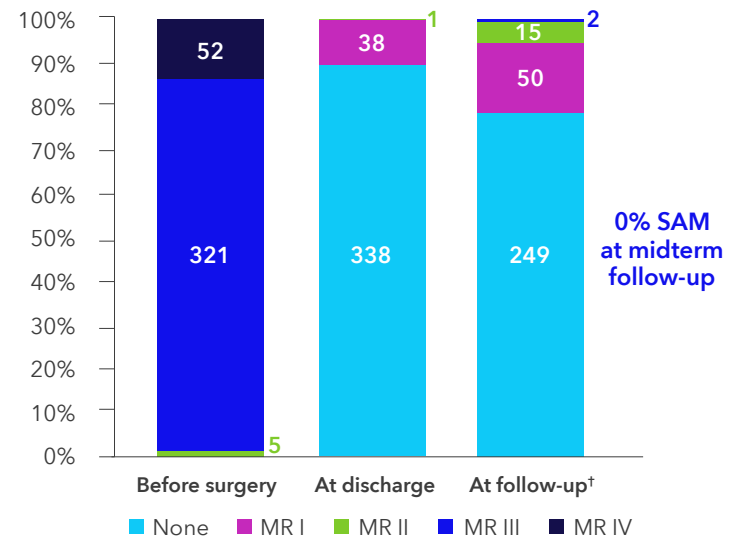


Reduces the risk of SAM – zero cases reported after mitral repair at midterm follow-up

Cumulative incidence of reoperation

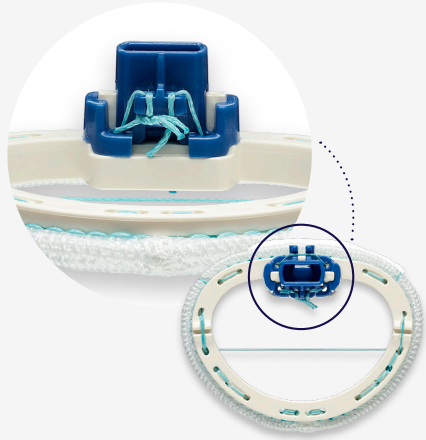


Degree of mitral valve regurgitation



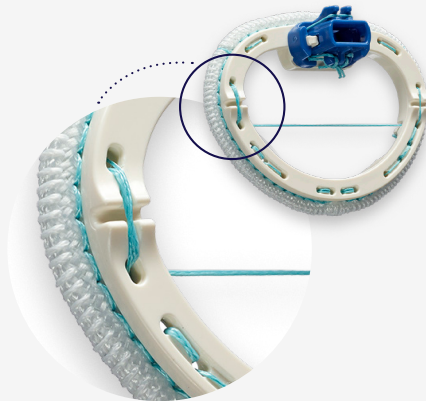
[†]Mean follow-up 2.4 ± 1.4 years.

Accessory enhancements



Low-profile open holder

Enables suture placement along the entire ring while fully accessing anatomy.



Clearly marked cut towers

Supports quick release of the ring through easy identification.



Stable handle-to-holder connection

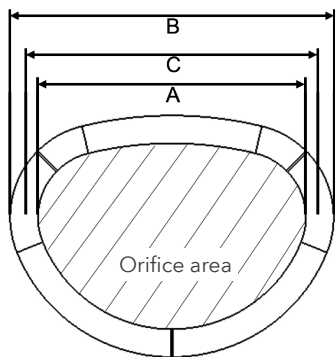
Allows for low-force, single-cut release, and remains securely attached during suturing.



Visual chordal reference line

Provides visual reference of annular plane when performing chordal repair.

SimuForm ring product information



A: Inner ring diameter
 B: Outer ring diameter
 C: Inner Stiffener diameter

Size (mm)	Product codes	"A" (mm)	"B" (mm)	Orifice area (mm ²)	Stiffener assembly inner diameter (mm)
24	7800RR24	23.1	31.0	290	24.6
26	7800RR26	25.0	32.9	340	26.5
28	7800RR28	26.9	34.9	390	28.5
30	7800RR30	28.9	36.8	460	30.4
32	7800RR32	30.7	38.7	480	32.3
34	7800RR34	32.7	40.6	560	34.2
36	7800RR36	34.6	42.6	640	36.2
38	7800RR38	36.6	44.5	730	38.1
40	7800RR40	38.5	46.4	810	40.0

SimuForm ring ordering information

Order number	Components and accessories
T7800P	SimuForm accessory tray
7800PS	Set of 9 SimuForm polysulfone sizers
7686	Annuloplasty handle (216 mm)
7686L	Annuloplasty handle, large (254 mm)
7686XL	Annuloplasty handle, XL (373 mm)



SimuForm
Sizers Tray

References

- 1 Sideris K, Burri M, Bordne J, et al. Repair of Mitral Valves with Severe Annular Dilatation and Abundant Leaflet Tissue Using a Prosthetic Ring with a Large Anterior-Posterior Diameter. *J Clin Med*. March 19, 2022;11(6):1709.
- 2 Jensen MO, Jensen H, Levine RA, et al. Saddle-shaped Mitral Valve Annuloplasty Rings Improve Leaflet Coaptation Geometry. *J Thorac Cardiovasc Surg*. September 2011;142(3):697-703.
- 3 Ryan LP, Jackson BM, Hamamoto H, et al. The Influence of Annuloplasty Ring Geometry on Mitral Leaflet Curvature. *Ann Thorac Surg*. September 2008;86(3):749-60.
- 4 Vergnat M, Jackson BM, Cheung AT, et al. Saddle-shape Annuloplasty Increases Mitral Leaflet Coaptation After Repair for Flail Posterior Leaflet. *Ann Thorac Surg*. September 2011;92(3):797-803.
- 5 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*. December 2007;134(6):1562-8.
- 6 Padala M, Hutchison RA, Croft LR, et al. Saddle shape of the mitral annulus reduces systolic strains on the P2 segment of the posterior mitral leaflet. *Ann Thorac Surg*. November 2009;88(5):1499-504.
- 7 Pierce EL, Bloodworth CH, Imai A, et al. Mitral Annuloplasty Ring Flexibility Preferentially Reduces Posterior Suture Forces. *J Biomech*. June 25, 2018;75:58-66.

SimuForm™ Semi-Rigid Annuloplasty Ring

Indications: The SimuForm semi-rigid annuloplasty rings are for use in patients undergoing surgery for diseased or damaged mitral valves. The SimuForm semi-rigid annuloplasty ring provides support for the mitral annulus and restricts expansion of the annulus.

Contraindications: Severe, generalized, or localized bacterial endocarditis, heavily calcified valves, greatly dilated annulus (not reducible by standard techniques), severe valvular dysfunction (not correctable by standard techniques), valvular retraction with severely reduced mobility, congenital malformations with lack of valvular tissue.

Warnings/Precautions/Adverse Events: Only surgeons who have received appropriate training in valve repair, including ring implant and sizing techniques, should use this device. Adverse events can include: uncorrected or recurrent regurgitation, stenosis, ring dehiscence, hemolysis (even with mild regurgitation), low cardiac output, heart block, systolic anterior motion (SAM) and left ventricular outflow tract obstruction (LVOTO), damage to coronary arteries, endocarditis, thrombosis, thromboembolism, anticoagulant-related hemorrhage, ring fracture, leaflet perforation, bleeding diathesis.

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

For a complete listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

Cardiovascular Group

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

LifeLine

CardioVascular Technical Support

Tel: 877.526.7890
Tel: 763.526.7890
Fax: 763.526.7888

rs.cstecsupport@medtronic.com

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