

MEMO 4D[®] Reshaping Mitral Repair



Designed to support a comprehensive range of techniques¹

MEMO 4D®

Reshaping Mitral Repair

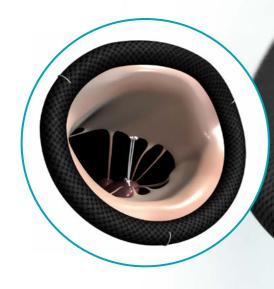
Designed to support a comprehensive range of techniques¹

ReChord: Chordal Guide System

Standardizes neochordae implantation^{2,3}

Proven Annular Dynamics

Truly physiological three-dimensional motion to ensure natural behavior^{4,5,6}



Unique Range of Sizes

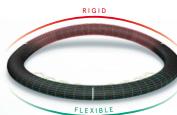
Up to size 42 mm to treat large annuli

Innovation Starts at the Core

Unique Nitinol Cell Structure

Stability and **Support**

Anterior rigidity and Posterior flexibility to **support systolic function**^{5,7}



Exclusive Gradual Saddle Shaping

Designed to accomodate the **physiological geometry** in enlarged annuli⁸



Progressive Increase of the Anteroposterior Diameter

Helps accommodate excess leaflet tissue and

reduces the risk of Systolic Anterior Motion (SAM)9

Unique Range of Sizes

A complete range of sizes to meet a size-specific repair principle. The 42 mm size is unique to MEMO 4D

 24*
 26
 28
 30
 32
 34
 36
 38
 40
 42

mm size range

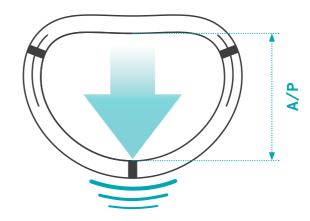




Large sizes are preferred by surgeons in facilitating repair in the presence of severe degenerative MR like Barlow's disease or big annuli.

Progressive Increase of the Anteroposterior Diameter

The progressive increase of the anteroposterior diameter of MEMO 4D, from size 34 to size 42, helps accommodate excess leaflet tissue, while reducing the risk of systolic anterior motion (SAM).9



Exclusive Gradual Saddle Shaping



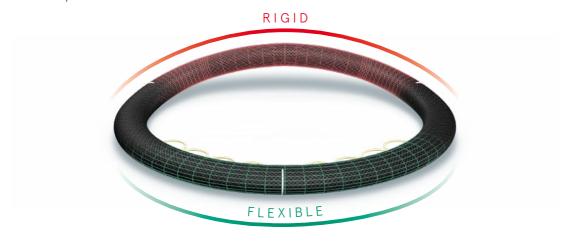
The anterior saddle shape is gradually enhanced from size 34 to size 42. Memo 4D is designed to restore the physiological geometry in enlarged annuli that have lost their three-dimensional profile.⁸

^{*} Made to order

Stability and Support

The right balance of rigidity and flexibility to cover a comprehensive range of mitral valve repair needs¹

MEMO 4D, semi-rigid annuloplasty ring, provides the stability and support to the annulus while providing dynamic flexibility of movement.¹



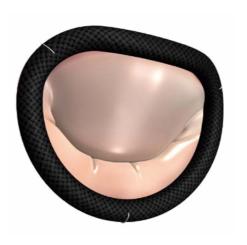
The natural annular dynamics of the MEMO platform is clinically proven and acknowledged^{5,7}

"MEMO 3D preserves annular dynamics and folding dynamics." 10

"MEMO 3D allows for contraction during systole, an increased depth of coaptation of the leaflets, and an improvement in annular orifice area during diastole." 11

Optimized Hemodynamics5,6,7

Truly physiological three-dimensional motion of the mitral annulus with a natural anterior/posterior to lateral/lateral relationship to maximize blood flow, ⁷ even five years after implantation. ^{5,13}





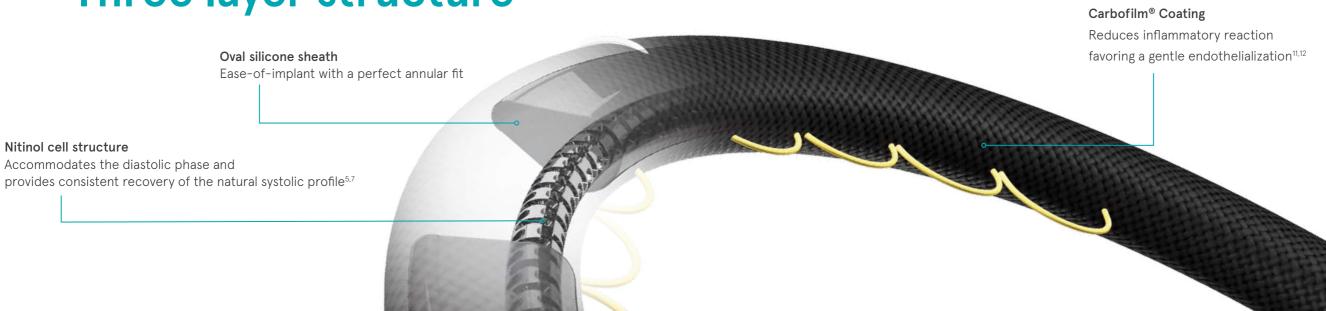


DIASTOLIC DYNAMICS

Maximized Hemodynamics 10

"In our study, the semi-rigid MEMO 3D annuloplasty ring was associated with a better hemodynamic at rest and during exercise and clinical status."

Three layer structure

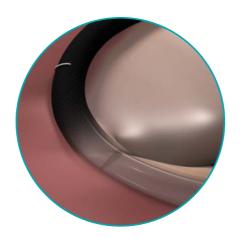


Ease-of-Implant

The "slim fit" ring designed to fit optimally to the patient annulus



Wide, streamlined silicone filler facilitates suturability



Designed to **optimally fit** to the mitral annulus

A Fully Versatile Holder

Chordal Window



Neochordae can pass through the aperture

One-Cut Removal



Single cut to unhook the whole holder

Designed to Facilitate MICS Approach



Low-profile holder



Ultra-slim template with two handles

ReChord System

A chordal sizing system that aims to standardize neochordae implantation without the need for physical measurement^{2,3}

A series of loops in the posterior region act as temporary reference elements for easier length sizing of chords for both anterior and posterior repair. The innovative system promotes standardized chord implantation, offering a reproducible technique while accelerating procedure times.^{3,14}



"The chordal guiding system markedly reduces the time of the procedure by facilitating sizing and knotting." ¹⁵

Information and accessories

Product ordering information

Ordering Number	Size	A [mm]*	N° Loops
4DM-24	24 **	24	6
4DM-26	26	26	6
4DM-28	28	28	6
4DM-30	30	30	6
4DM-32	32	32	6
4DM-34	34	34	8
4DM-36	36	36	8
4DM-38	38	38	8
4DM-40	40	40	8
4DM-42	42	42	8



Accessories ordering information

Ordering Number	Name	Description	
ICV0664	Uni Handle	Universal Bendable Handle	
ICV1342	Extended Uni Handle	Universal Bendable Handle for MICS	
ICV1357	Annuloplasty Ring Sizer Set	Complete Sizer Set (24 to 42 mm)	
ICV1358	Annuloplasty Ring Accessory Tray	Empty Instrument Tray	







MEMO 4D Sizer Set Now with more transparent heads for a better visibility

References

- Nasso et al., "Three-Year Results of Repaired Barlow Mitral Valves via Right Minithoracotomy versus Median Sternotomy in a Randomized Trial." Cardiology 2014;128:97-105
- Wan et al., "Mitral valve repair using a semirigid ring: patient selection and early outcomes." Asian Cardiovascular & Thoracic Annals 0(0) 1–6 2016
- Prinzing et al., "Initial Experience With a New Mitral Ring Designed to Simplify Length Determination of Neochords." Ann Thorac Surg 2018;105:1784-9
- 4. Nishi et al., "Annular dynamics after mitral valve repair with different prosthetic rings: A real-time threedimensional transesophageal echocardiography study." Surg Today 2016 Sep;46(9):1083-90
- 5. Ryomoto et al., "Physiological mitral annular dynamics preserved after ring annuloplasty in mid-term period." Gen Thorac Cardiovasc Surg (2017) 65:627–632
- 6. Fattouch et al., "A Comparison of 2 Mitral Annuloplasty Rings for Severe Ischemic Mitral Regurgitation: Clinical and Echocardiographic Outcomes." Semin Thorac Cardiovasc Surg 2016 Summer; 28(2):261–268
- 7. Nishi et al., "Annular dynamics of memo3D annuloplasty ring evaluated by 3D transesophageal echocardiography." Gen Thorac Cardiovasc Surg. 2018 Apr;66(4):214-219
- 8. Lee et al., "Quantitative Analysis of Mitral Valve Morphology in Mitral Valve Prolapse With Real-Time 3-Dimensional Echocardiography Importance of Annular Saddle Shape in the Pathogenesis of Mitral RegurgitationCirculation." 2013;127:832-841
- Adams et al., "Large Annuloplasty Rings Facilitate Mitral Valve Repair in Barlow's Disease." Ann Thorac Surg 2006;82:2096–101
- Ryomoto et al., "Is Physiologic Annular Dynamics Preserved After Mitral Valve Repair With Rigid or Semirigid Ring?" Ann Thorac Surg 2014;97:492-8
- 11. Bruno et al., "Early Clinical Experience and Echocardiographic Results With a New Semirigid Mitral Annuloplasty Ring: The Sorin Memo 3D."

 Ann Thorac Surg 2009;88:1492–8
- 12. Della Barbera et al., "Sovering annuloplasty rings: Experimental pathology in the sheep model." Cardiovascular Pathology 14 (2005) 96–103
- 13. Santarpino G et al., "First-in-man implantation of a Sorin MEMO 3D ring: Mitral annular flexibility is still preserved at 5 years of follow-up!" Int. I Cardiol. 2012 Dec 14
- Wan et al., "Mitral valve repair using a semirigid ring: patient selection and early outcomes." Asian Cardiovasc Thorac Ann 2016 Sep;24(7):647-52
- 15. G. Szabó et al., "The Novel Livanova 3D Rechord Semirigid Ring Facilitates Mitral Valve Repair With Artificial Chords: A Matched Pair Analysis." Thorac cardiovasc Surg 2018; 66(S 01): S1-S110

^{*} Inner metal core diameter

^{**} Made to order

INDICATIONS: <u>EUROPE and US</u>: The MEMO 4D annuloplasty ring is intended for correction of mitral insufficiencies, steno-insufficiencies or acquired mitral insufficiencies (type I, type II, type III) with dilatation and deformation of the mitral annulus. The decision to undertake a mitral valve repair must remain with the surgeon after having evaluated short- and long-terms risks and benefits towards alternative procedures and on the visual inspection of the lesion in the individual case.

TOP POTENTIAL SIDE EFFECTS: The use of prosthetic annuloplasty rings is associated with serious potential complications, which include: death, reoperation and explants, residual or recurrent regurgitation,

stenosis, thromboembolism, hemolysis, atrio-ventricular block, endocarditis, low cardiac output, failure or degeneration of the natural valvular apparatus due to progression of disease, partial/total ring dehiscence, partial dislodgment of the ring from its site of attachment, malfunction of the ring due to distortion or fracture at implant or physical or chemical deterioration of ring components; fabric tearing due to the use of cutting needles or serrated forceps, systolic anterior motion (SAM) and left ventricular outflow tract obstruction (LVOTO), prosthesis thrombosis, infection.

- CONTRAINDICATIONS: The annuloplasty rings should not be used in the case of:
 Severe organic lesions with retraction of chordae tendinae.
- Congenital malformations with limited valvular tissue. Extensive calcification of valve leaflets.
- Evolving bacterial endocarditis. **MRI conditional.**



Health innovation that matters

Manufactured by:

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