



MITRAL
ANNULOPLASTY RING

MEMO 3D™

Truly 3D motion



 **CORCYM**
WE TAKE LIFE TO HEART



MEMO 3D™ DESIGN

Unique to its core³

CORCYM Memo 3D annuloplasty ring has been engineered to provide a unique solution to cover a comprehensive range of mitral valve repair needs.^{1,2,3}

The unique core of Memo 3D provides firm support to the mitral annulus while allowing a 3D motion that aims to mimick that of the native mitral annulus.

The innovative design of Memo 3D provides desirable outcomes*, combined with enhanced hemo and biocompatibility.^{4,5}

* Based on CORCYM post-market surveillance, ring-related mitral regurgitation is expected to occur between 1 and 10 times per 10000 device population.

1. 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.

2. Fattouch et al., A Comparison of 2 Mitral Annuloplasty Rings for Severe Ischemic Mitral Regurgitation: Clinical and Echocardiographic Outcomes. *SeminThoracicSurg* 28:267-268 | 2016.

3. 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.

4. Vallana et al., Carbofilm: Present and Future Applications in Biomedical Devices, *Ceramics International* 19 (1993) 169-179.

5. Della Barbera et al., Sovering annuloplasty rings: Experimental pathology in the sheep model, *Cardiovascular Pathology* 14 (2005) 96-103.

Technical claims are supported by CORCYM data on file.

UNIQUE SUPER-ELASTIC ALLOY CORE¹

The exclusive alloy core cell design is a laser-cut one-piece structure that enables annular dynamics mimicking those of a physiological annulus.

The same precision laser-cut technology is also used to create CORCYM's innovative Perceval sutureless aortic prosthesis.

SHAPE MEMORY

Memo 3D's superelastic alloy core "remembers" its prefixed shape, meaning it returns to its original form even after being flexed back and forth.

This shape memory is important as it provides recovery of the systolic profile and restores the natural systolic diameter ratio.^{2,3}

THE RIGHT BALANCE OF RIGIDITY AND FLEXIBILITY TO SUPPORT BOTH DEGENERATIVE AND FUNCTIONAL MITRAL REPAIR.^{1,4,5}

The Memo 3D semi-rigid annuloplasty ring has been engineered to give the stability needed to support the annulus while ensuring flexibility of movement.

The innovative superelastic alloy cell structure is optimized to provide a progressive degree of flexibility from the anterior to the posterior portion of the ring, to allow three-dimensional motion and potentially reduce stress on the repair.²

THREE LAYER STRUCTURE

Ease of implant with good visibility, placement and attachment to ensure proper annular fit.

The oval silicone sheath makes it easy to penetrate the ring with a needle and suture it in place.⁶



1. 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.

2. Nishi et al, Annular dynamics of memo3D annuloplasty ring evaluated by 3D transesophageal echocardiography. *General Thoracic and Cardiovascular Surgery*, Received: 22 August 2017 / Accepted: 9 January 2018.

3. Ryomoto et al, Physiological mitral annular dynamics preserved after ring annuloplasty in mid-term period. *Gen Thorac Cardiovasc Surg* (2017) 65:627–632.

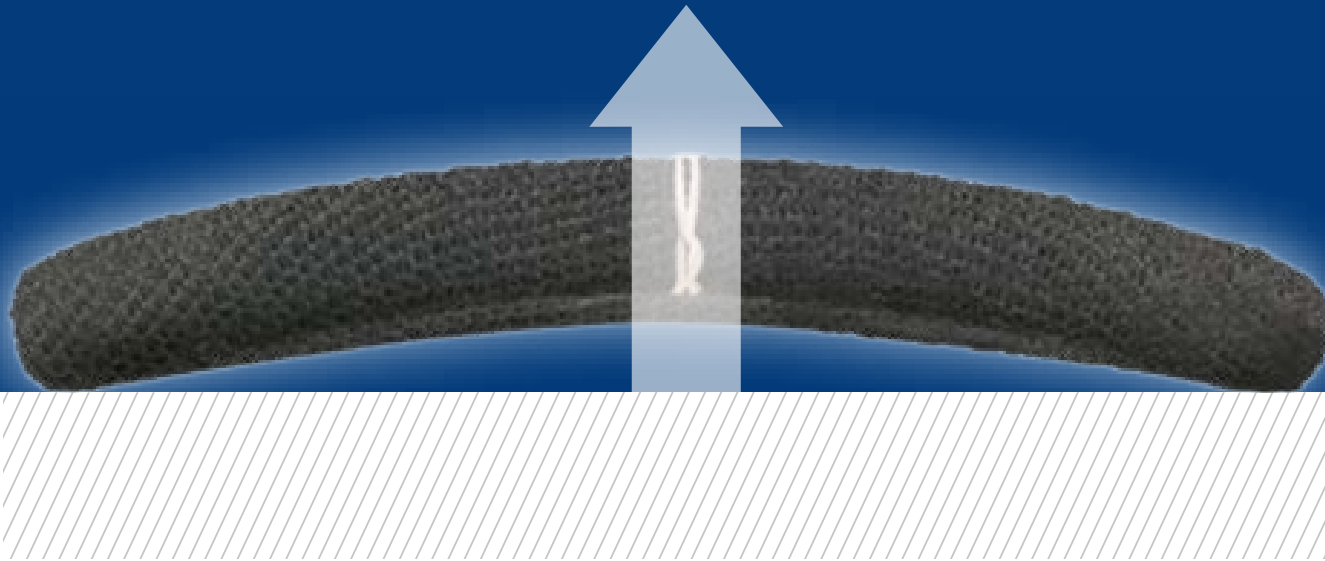
4. Nasso et al, Three-Year Results of Repaired Barlow Mitral Valves via Right Minithoracotomy versus Median Sternotomy in a Randomized Trial. *Cardiology* 2014;128:97–105.

5. Fattouch et al, A Comparison of 2 Mitral Annuloplasty Rings for Severe Ischemic Mitral Regurgitation: Clinical and Echocardiographic Outcomes. *SeminThoracicSurg*28:261–268 | 2016.

6. Glaubet al, Minimally invasive mitral valve repair using a semi-rigid annuloplasty ring with a new chordal sizing system: the Memo3D ReChord. *Ann Cardiothorac Surg* 2015;4(3):298-300.

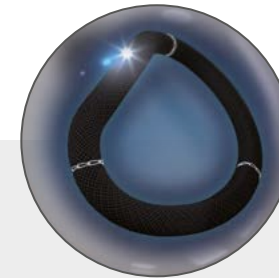
PERFORMANCE

The reflection of the mitral annulus

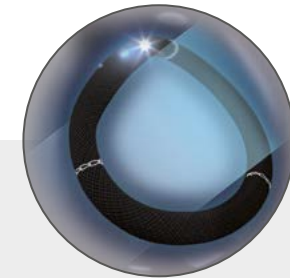


SYSTOLIC REMODELING AND DIASTOLIC DYNAMICS CONCEPT

Truly three-dimensional motion of the mitral annulus with an anterior/posterior to lateral/lateral relationship to maximize blood flow,^{1,2} even more than five years after implantation.³



Systolic remodelling
optimized coaptation and
reduced stress¹



Diastolic dynamics
optimized
hemodynamics²

TRULY 3D MOTION

The truly 3D motion of the ring during the cardiac cycle preserves the non-planar saddle shape geometry of the annulus.

Recent clinical data have demonstrated that Memo 3D is able to accommodate the physiological saddle shape of the mitral annulus throughout the cardiac cycle upon implantation.^{1,2}

CARBOFILM™ COATING

The bio/hemocompatible properties of the unique Carbofilm™ coating allow complete endothelialization, prevent inflammatory reaction and scar tissue formation. Designed to maintain physiological dynamics in the long term.^{3,4,5}



1. Nishi et al., Annular dynamics of memo3D annuloplasty ring evaluated by 3D transesophageal echocardiography. *General Thoracic and Cardiovascular Surgery*, Received: 22 August 2017 / Accepted: 9 January 2018.

2. Ryomoto et al., Physiological mitral annular dynamics preserved after ring annuloplasty in mid-term period. *Gen Thorac Cardiovasc Surg* (2017) 65:627–632.

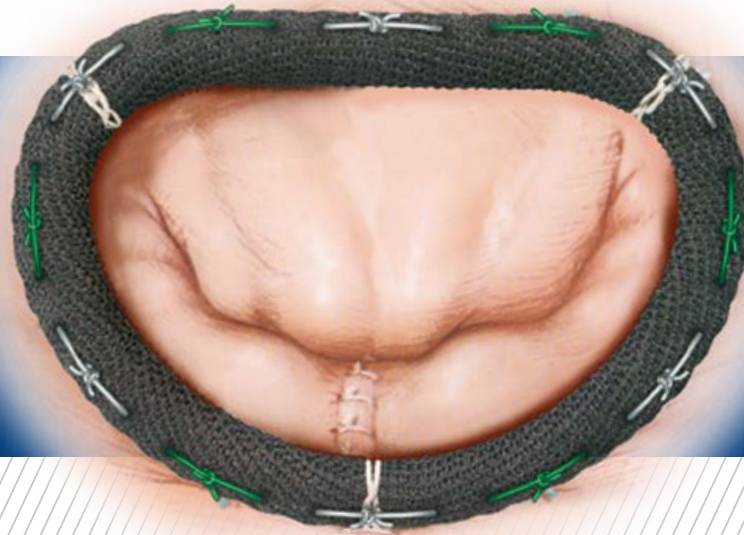
3. Santarpino et al., First-in-man implantation of a Sorin Memo 3D ring: Mitral annular flexibility is still preserved at 5 years of follow-up! *International Journal of Cardiology* 159 (2012) e23–e24.

4. Vallana et al., Carbofilm: Present and Future Applications in Biomedical Devices, *Ceramics International* 19 (1993) 169-179.

5. Della Barbera et al., Sovering annuloplasty rings: Experimental pathology in the sheep model, *Cardiovascular Pathology* 14 (2005) 96-103.

IMPLANTATION

Ease of use and implant



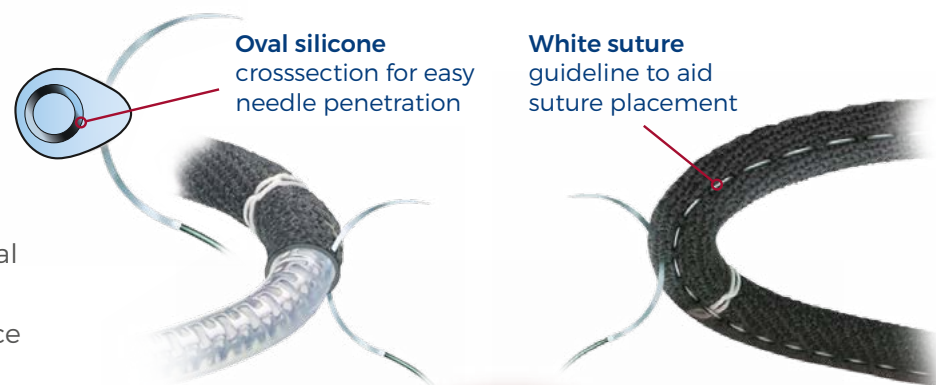
PROPER ANNULAR FIT AND VISUALIZATION

SILICONE RING FOR EASY NEEDLE PENETRATION AND WHITE SUTURES AS GUIDELINES

The Memo 3D semirigid annuloplasty ring facilitates implantation with proper visibility, placement, and attachment.

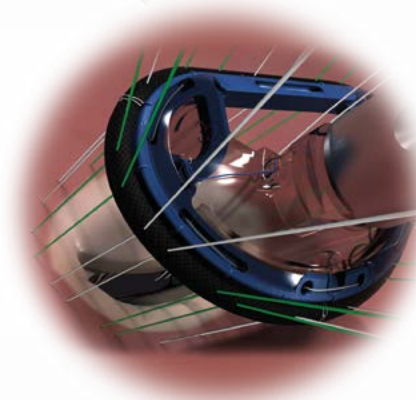
The oval cross section of the silicone sheath provides more material for the needle to penetrate in.

White suture guidelines on the underside provide a visual reference point while suturing.



HOLDER

The versatile holder has been designed to facilitate the implantation procedure. The ring is attached to a template that can be removed together with the holder or temporarily left in position to be removed after knot tying.



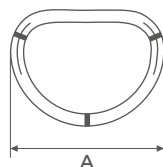
MICS sizers

The set of sizers have been specifically designed to optimize sizing also during minimally invasive procedures where surgical site visualization is compromised.



PRODUCT ORDERING INFORMATION

CODE	REF	SIZE	A [MM]	ORIFICE AREA (CM ²)
ICV0966	SMD 24	24	24	2.30
ICV0967	SMD 26	26	26	2.78
ICV0968	SMD 28	28	28	3.28
ICV0969	SMD 30	30	30	3.78
ICV0970	SMD 32	32	32	4.39
ICV0971	SMD 34	34	34	4.98
ICV0972	SMD 36	36	36	5.67
ICV0973	SMD 38	38	38	6.34



ACCESSORIES ORDERING INFORMATION

CODE	NAME	DESCRIPTION
ICV0664	Uni Handle	Universal Bendable Handle
ICV1342	Extended Uni Handle	Universal Bendable Handle for MICS
ICV1340	Annuloplasty Ring Sizer Set	Complete Sizer Set (24 to 38 mm)
ICV1343	Annuloplasty Ring Accessory Tray	Empty Instrument Tray



INTENDED USE/INDICATIONS

Europe, US, Canada: Memo 3D device is intended to reshape and support the mitral annulus after the surgical repair. Memo 3D device is indicated for use in patients suffering from congenital or acquired mitral insufficiencies or steno-insufficiencies with dilatation and deformation of the mitral annulus.

Australia: Memo 3D device is intended for correction of mitral insufficiencies or steno-insufficiencies. The use of the Memo 3D device is indicated for correction of congenital or acquired mitral insufficiencies with dilatation and deformation of the mitral annulus.

KEY 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.

KEY WARNINGS

The annuloplasty ring is a single-use device and is intended for single patient use only. Do not attempt to clean, resterilize, or reuse any prosthesis. Do not sterilize the annuloplasty ring or accessory instrumentation by ethylene oxide (EtO) or radiation methods. The device is not suitable for tricuspid valve repair. Use only appropriate accessories supplied by Corcym Sales Organization. The use of sizers provided by other manufacturers or the use of the sizing technique employed for another manufacturer's annuloplasty ring may result in misleading sizing information.

TOP POTENTIAL SIDE EFFECTS

The use of mechanical prosthetic annuloplasty rings is associated with serious potential complications, which include: death; reoperation and explant; residual or recurrent regurgitation; stenosis; thromboembolism; hemolysis; atrio-ventricular block; endocarditis; low cardiac output; right heart failure; failure or degeneration of the natural valvular apparatus due to progression of disease, endocarditis, incomplete/inadequate repair of the valvular and subvalvular structures; obliteration of the circumflex coronary artery due to surgical suturing; partial/total ring dehiscence; complications related to prolonged bypass, aortic cross-clamping, and inadequate myocardial protection; 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; bleeding complications related to the use of anticoagulant therapy; systolic anterior motion (SAM) and left ventricular outflow tract obstruction (LVOTO); prosthesis thrombosis; infection.

MRI conditional

For professional use. Instructions for Use are available upon request through the manufacturer's website. Not approved in all geographies. Follow your labeling.



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