



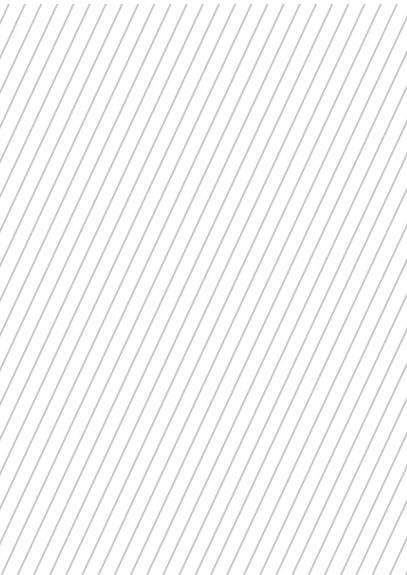
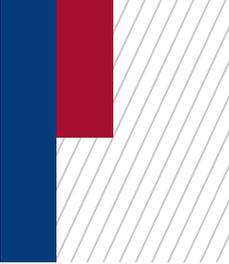
MEMO 3D™ RECHORD

MITRAL
ANNULOPLASTY RING

Ready to repair



 **CORCYM**
WE TAKE LIFE TO HEART



**CORCYM MEMO 3D™ RECHORD
HAS BEEN ENGINEERED TO PROVIDE
A UNIQUE SOLUTION TO COVER
A COMPREHENSIVE RANGE
OF MITRAL VALVE REPAIR NEEDS.^{1,2,3}**

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*28:261-268 | 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.

Technical claims are supported by CORCYM data on file.

MEMO 3D RECHORD

Designed to standardize mitral repair

Memo 3D ReChord

is an advanced repair device designed for desirable Patient outcomes^{1,2*}, while facilitating the surgical procedure. Memo 3D ReChord, with its innovative chordal guiding system, turns artificial chordae replacement into standard procedure.¹



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

1. Glauber et 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.
2. Wan et al, Mitral valve repair using a semirigid ring: patient selection and early outcomes. *Asian Cardiovascular & Thoracic Annals* 0(0) 1-6 The Author(s) 2016.



DESIGN

Unique to its core¹

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}

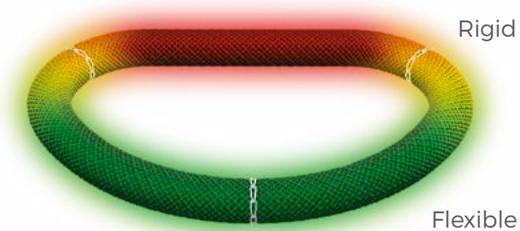
The Memo 3D semi-rigid annuloplasty ring has been engineered to give the stability needed to support the annulus while ensuring flexibility of movement.

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.

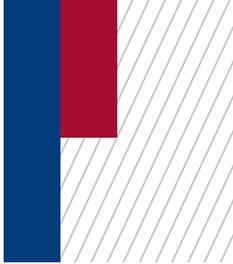
2. Nishi et al., Annular dynamics of memo3D annuloplasty ring evaluated by 3D transesophageal echocardiography. *General Thoracic and Cardiovascular Surgery*, Received: 22 August 2017 / Accepted: 9 January 2018.

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

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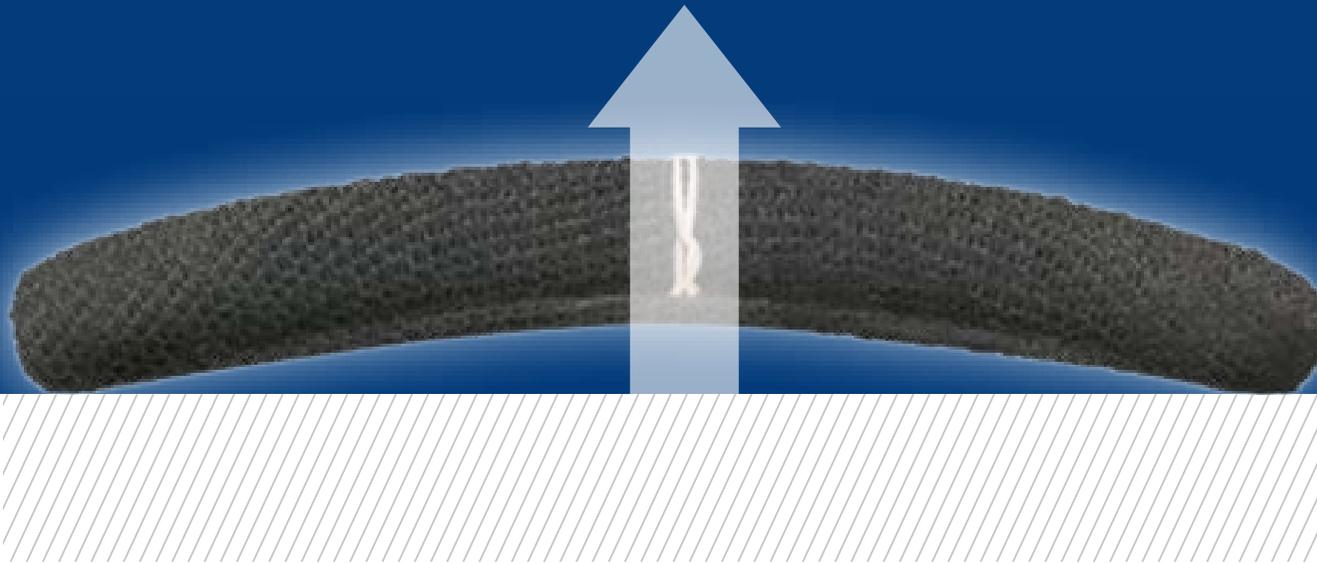
5. Fattouch et al., A Comparison of 2 Mitral Annuloplasty Rings for Severe Ischemic Mitral Regurgitation: Clinical and Echocardiographic Outcomes. *SeminThoracicSurg*28:261-268 | 2016.

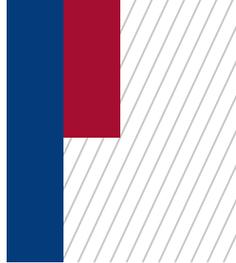
6. Glaubet et al., Minimally invasive mitral valve repair using a semi-rigid annuloplasty ring with a new chordal sizing system: the Memo3D ReChord. *Ann Cardiothorac Surg* 2015;4(3):298-300.



PERFORMANCE

The reflection of the mitral annulus



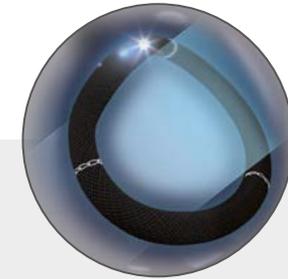


SYSTOLIC REMODELING AND DIASTOLIC DYNAMICS CONCEPT

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.

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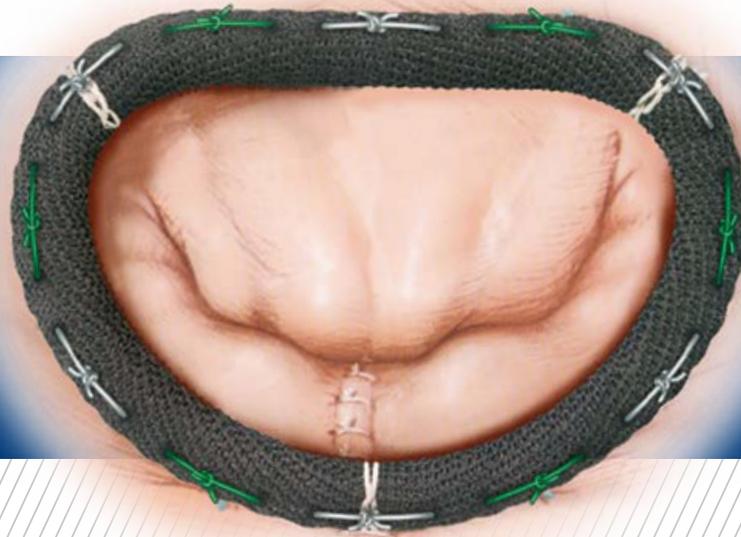
3. Santarpino et al., First-in-man implantation of a Sorin Memo 3D ring: Mitral annular flexibility is still preserved at 5 years of follow-up! *International Journal of Cardiology* 159 (2012) e23–e24.

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

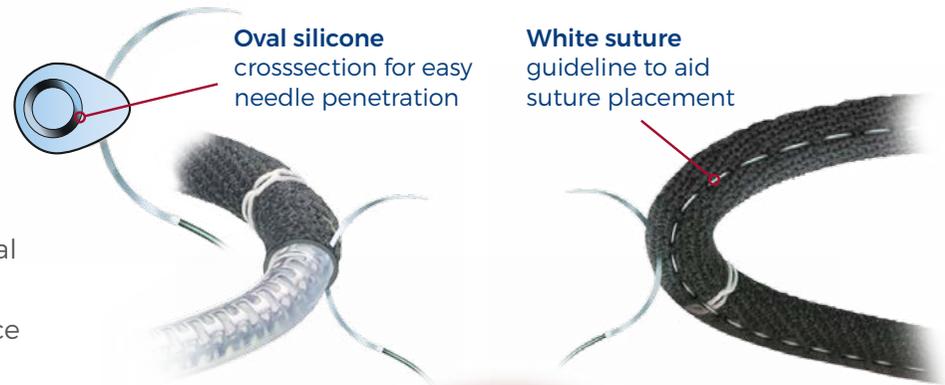
Ease of use and implant



PROPER ANNULAR FIT AND VISUALIZATION

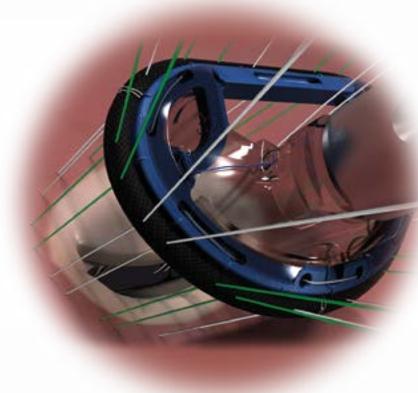
SILICONE RING FOR EASY NEEDLE PENETRATION AND WHITE SUTURES AS GUIDELINES

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.



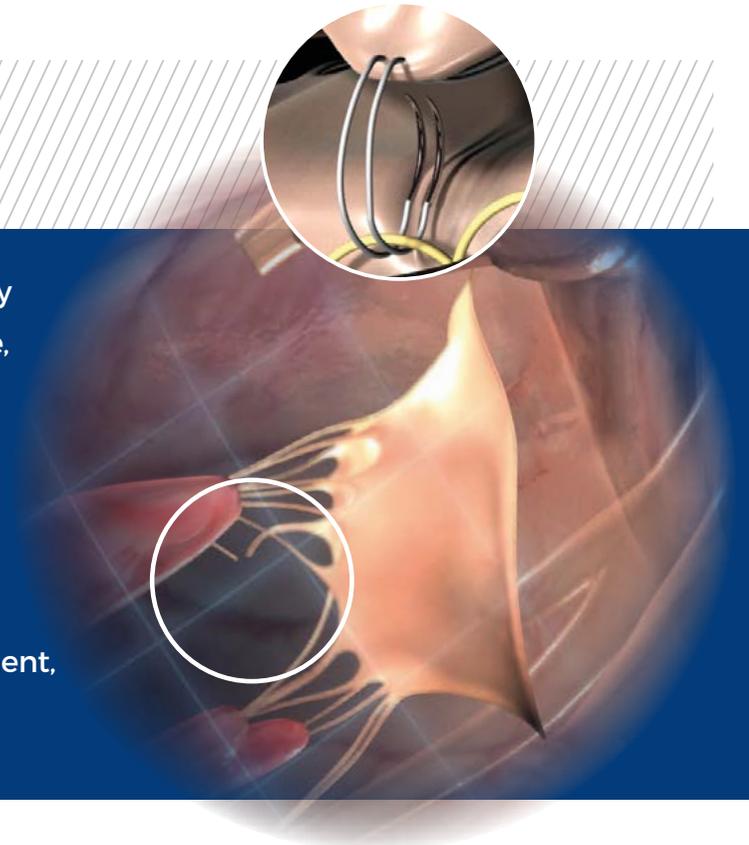
INNOVATION

Guiding Standards

MEMO 3D RECHORD is an advanced repair device technology designed for desirable Patient outcomes* while facilitating the surgical procedure, thanks to its innovative chordal guiding system that makes artificial chordae replacement a standard procedure.¹

Memo 3D ReChord incorporates a series of loops in the posterior region that act as temporary reference points when sizing the chords' length.

The innovative chordal guiding system promotes standardized chordae replacement, while reducing procedural time.^{1,2}



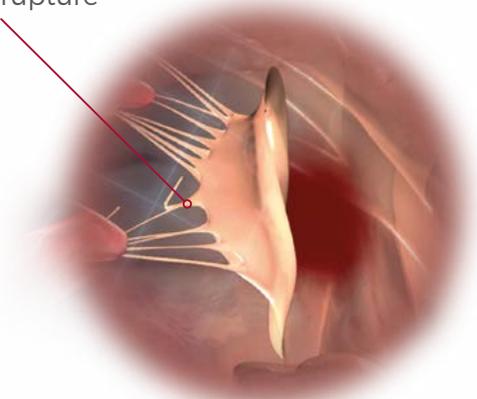
Facilitating and standardizing
the implantation procedure.¹

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

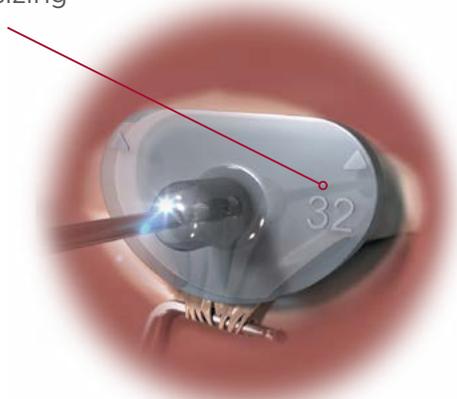
1. Glauber et al, Minimally invasive mitral valve repair using a semi-rigid annuloplasty ring with a new chordal sizing system: the Memo3D ReChord. *Ann Cardiothorac Surg* 2015;4(3):298-300.
2. Wan et al, Mitral valve repair using a semirigid ring: patient selection and early outcomes. *Asian Cardiovascular & Thoracic Annals* 0(0) 1-6 The Author(s) 2016.

Implantation procedure

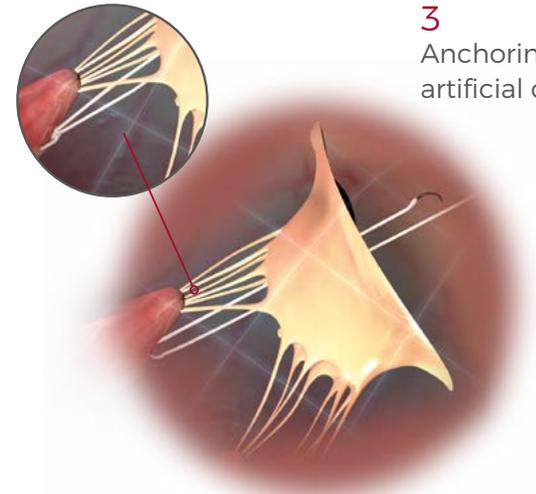
1
Mitral regurgitation:
chordal rupture



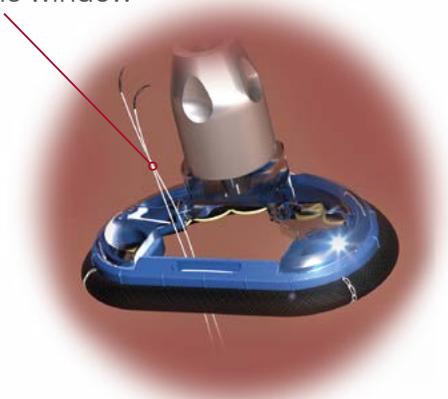
2
Annuloplasty
ring sizing



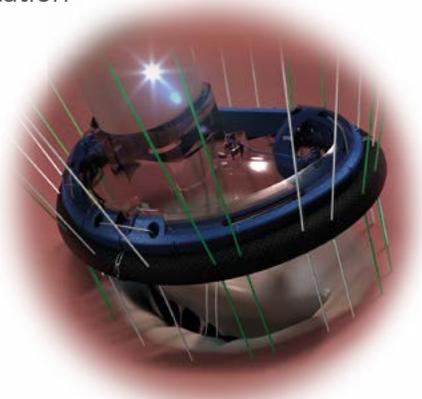
3
Anchoring of the
artificial chord



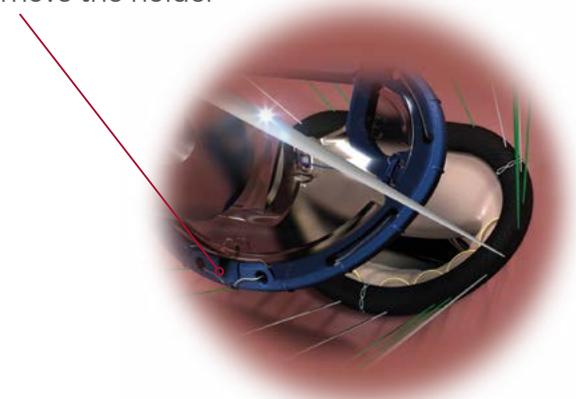
4
Chord should be passed
through the window



5
Ring parachuting and
implantation



6
Cut at the P2 area and
remove the holder

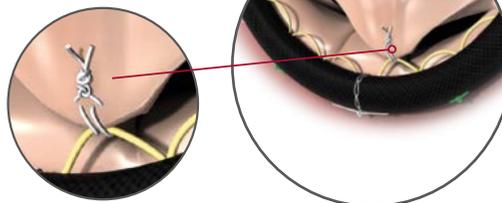


Implantation procedure

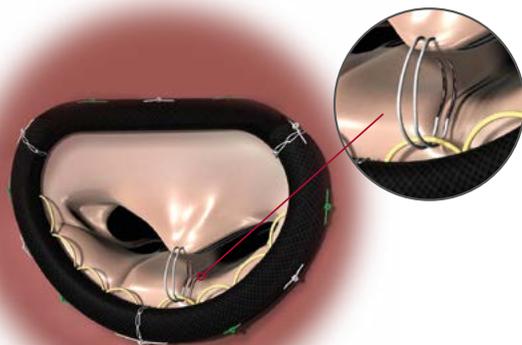
7
Tie the knots tight



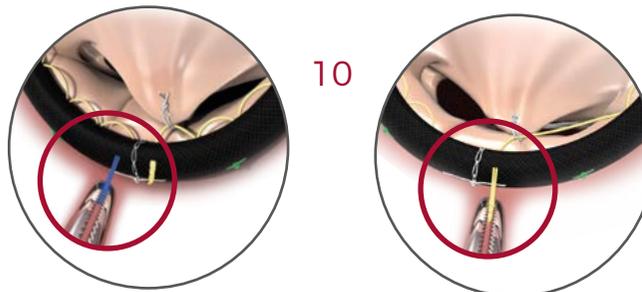
9
Knots are tied at the annular level



8
Artificial chord through the reference element on the Memo 3D ReChord



10



Step 1: pull the blue thread first

Step 2: then pull the yellow thread

No cutting is needed

11
Truly 3D motion of the mitral annulus¹⁻³



12
Fast and simplified procedures for desirable Patient outcomes^{4,5*}



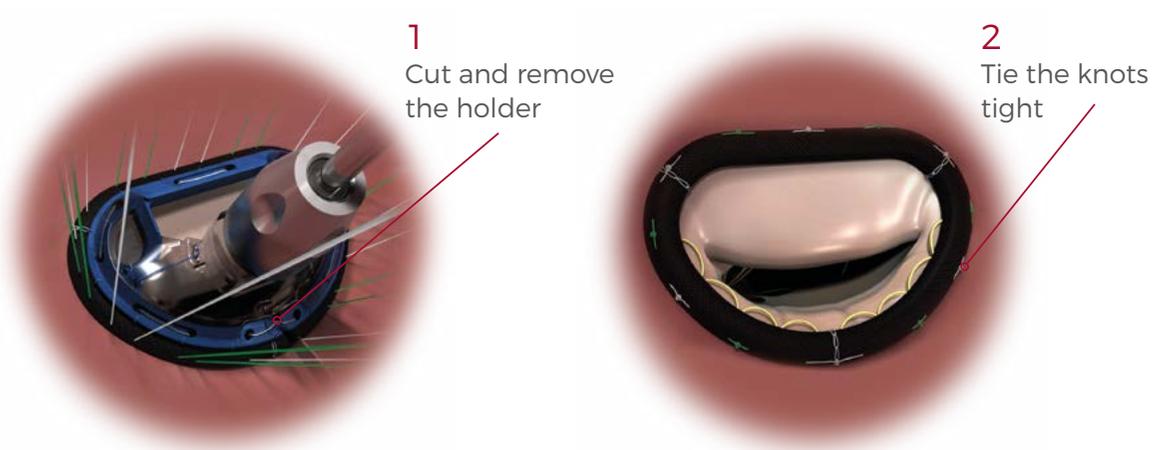
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Holder

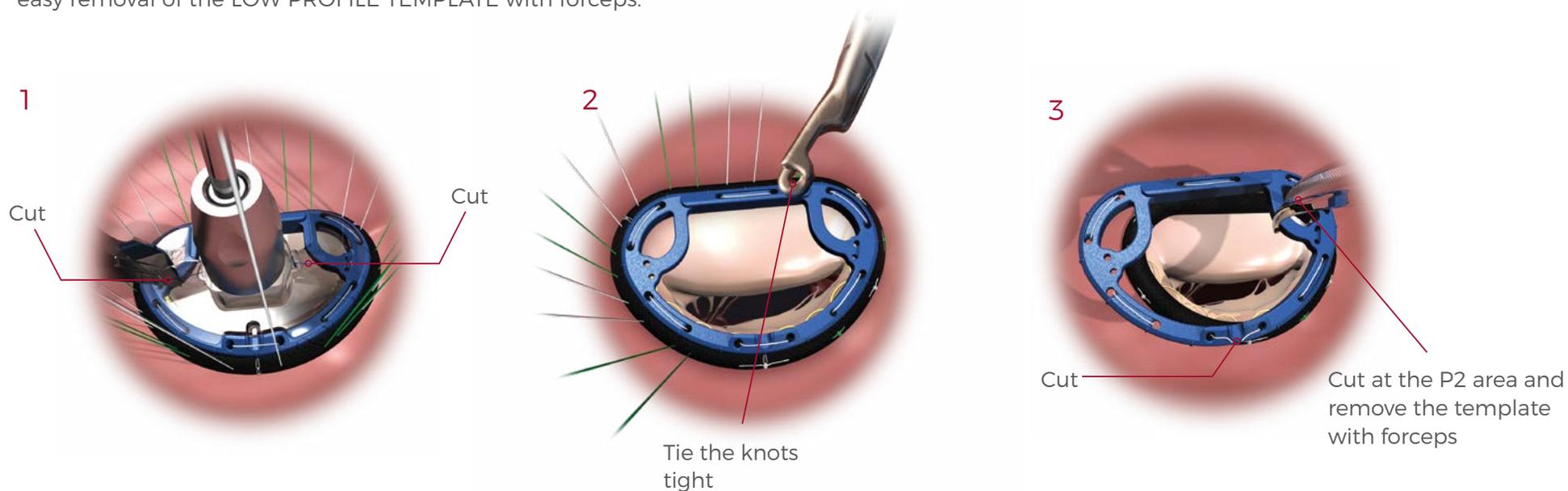
ONE-STEP REMOVAL

Remove all with one single cut: fast removal, user friendly (one cut only at the P2 area).



TWO-STEP REMOVAL

For those that prefer to have a rigid frame when tying the knots (avoid purse string effect and stress on the structure) and to protect the loops from the knotpusher when addressing the valve in MICS. Specifically designed handle for an easy removal of the LOW PROFILE TEMPLATE with forceps.



CLINICAL HIGHLIGHTS

From the first published experience¹

“The length of the neochordae obtained will exactly match the plane of the native annulus at the coaptation point.”¹

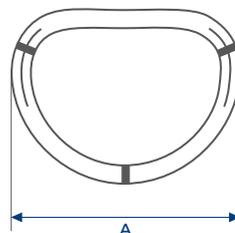
“This is a simple and reproducible technique, suitable for both anterior and posterior leaflet prolapse, which restores leaflet motion and ensures a large surface of coaptation.”¹

“According to our experience, the temporary chordal guide system allows a correct implantation of PTFE neochordae without the need for chordal measurement, short operative times and doesn't require a long learning process. In our opinion, its use might standardize the “respect rather than resect” mitral valve repair technique, further facilitating a MIMV surgical approach.”¹

1. Glauber et 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.

PRODUCT ORDERING INFORMATION

CODE	REF	SIZE	A (MM)	ORIFICE AREA (CM ²)
ICV1330	MRCS24	24	24	2.30
ICV1331	MRCS26	26	26	2.78
ICV1332	MRCS28	28	28	3.28
ICV1333	MRCS30	30	30	3.78
ICV1334	MRCS32	32	32	4.39
ICV1335	MRCS34	34	34	4.98
ICV1336	MRCS36	36	36	5.67
ICV1337	MRCS38	38	38	6.34



ACCESSORIES ORDERING INFORMATION (not provided sterile)

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

Australia: Memo 3D ReChord device is intended for correction of mitral insufficiencies or steno-insufficiencies. The use of the Memo 3D ReChord 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. 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. Do not cut the yellow loops of the RCS. Do not pull the blue and yellow knots of the RCS threads contemporarily. Do not attempt to remove the yellow thread loops by pulling the yellow knot without having completely removed the blue thread first.

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.



Manufactured by:

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Corcym S.r.l. previously Sorin Group Italia S.r.l.



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