



**MEMO 4D™**

MITRAL  
ANNULOPLASTY RING

Reshaping  
mitral repair



## MEMO 4D™

Designed to support  
a comprehensive range  
of techniques<sup>1</sup>



# RESHAPING MITRAL REPAIR

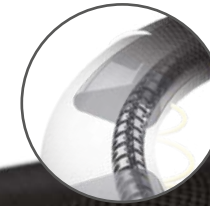
## ReChord: CHORDAL GUIDE SYSTEM

Standardizes neochordae  
implantation<sup>2,3</sup>



## PROVEN ANNULAR DYNAMICS

Truly physiological  
three-dimensional motion  
to ensure natural behavior<sup>4,5,6</sup>

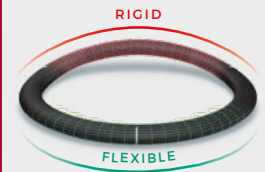


## INNOVATION STARTS AT THE CORE

Unique Nitinol Cell Structure

## STABILITY AND SUPPORT

Anterior rigidity and  
Posterior flexibility  
to support systolic function<sup>5,7</sup>



## EXCLUSIVE GRADUAL SADDLE SHAPING

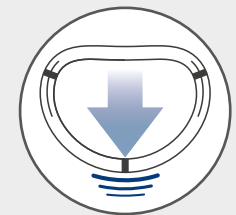
Designed to accommodate the  
physiological geometry  
in enlarged annuli<sup>8</sup>



42

## UNIQUE RANGE OF SIZES

Up to size 42 mm  
to treat large annuli

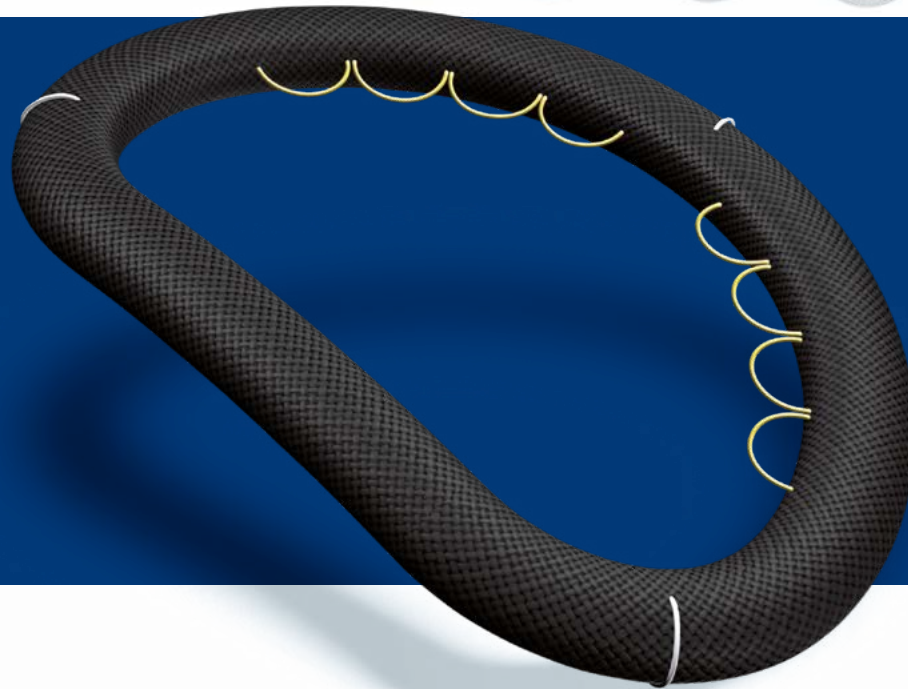


## PROGRESSIVE INCREASE OF THE ANTEROPOSTERIOR DIAMETER

Helps accommodate excess leaflet tissue and  
reduces the risk of Systolic Anterior Motion (SAM)<sup>9</sup>

## 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.

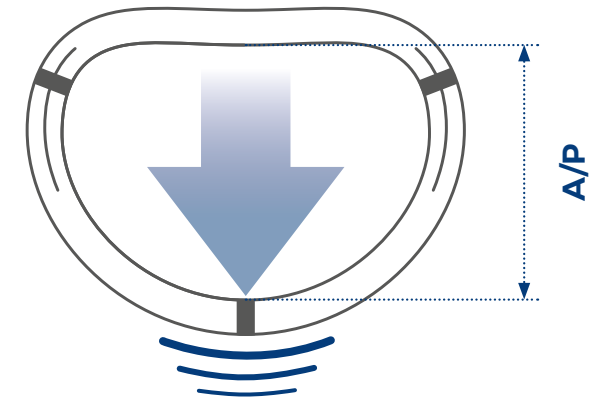


Large sizes are preferred by Surgeons in facilitating repair in the presence of severe degenerative MR like Barlow's disease or big annuli.<sup>9</sup>

\* Made to order

# Progressive Increase of the Anteroposterior Diameter

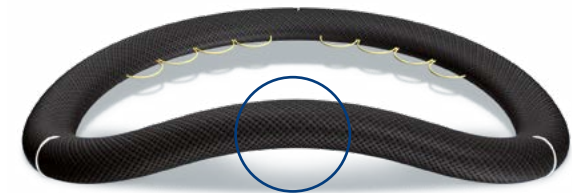
**THE PROGRESSIVE INCREASE OF THE ANTEROPOSTERIOR DIAMETER OF MEMO 4D,** from size 34 to size 42, helps accommodate excess leaflet tissue, while reducing the risk of systolic anterior motion (SAM).<sup>9</sup>



## 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.<sup>8</sup>



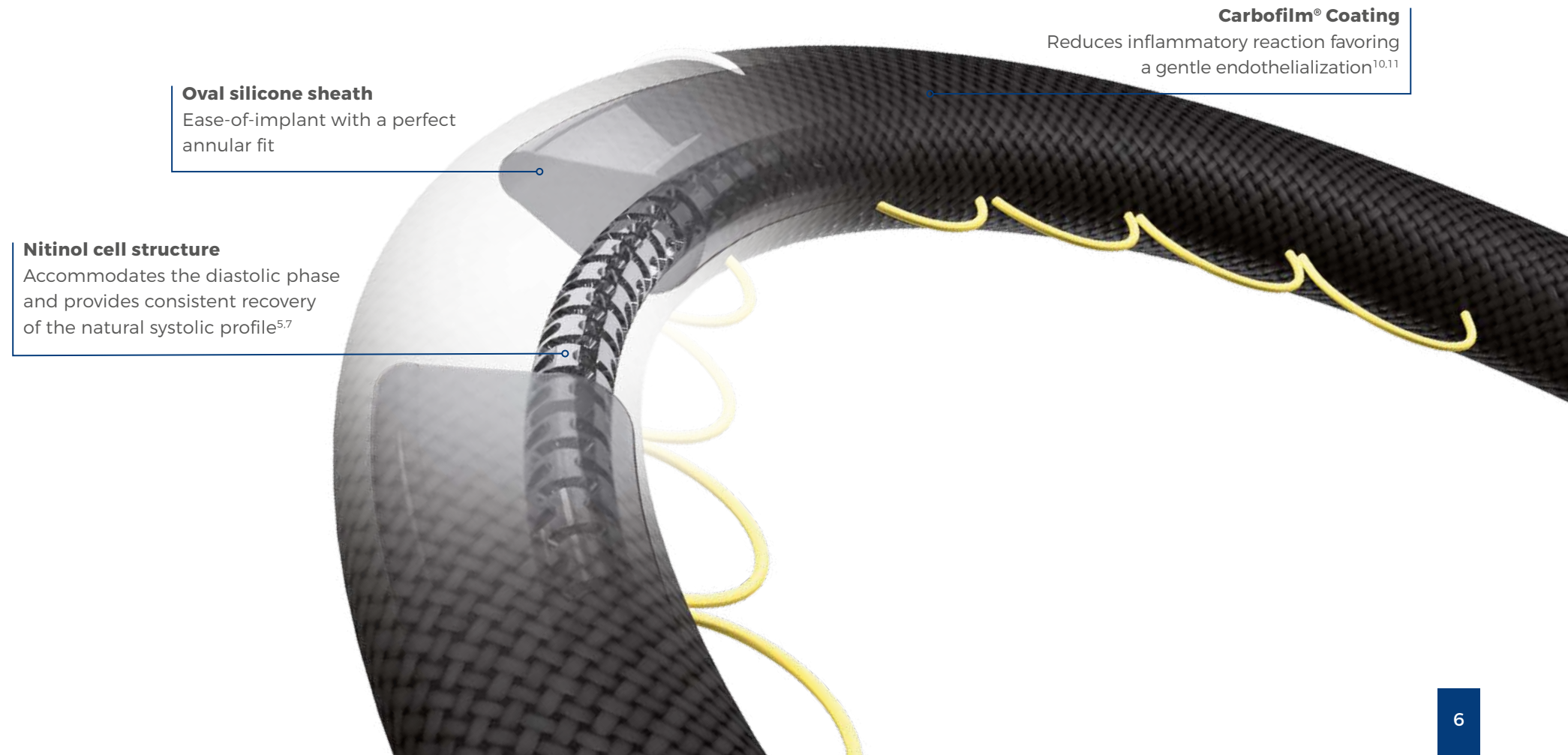
The anterior saddle shape is gradually enhanced from size 34 to size 42. Memo 4D is designed to restore the physiological geometry in enlarged annuli that have lost their three-dimensional profile.<sup>8</sup>



# Three layer structure

**THE RIGHT BALANCE OF RIGIDITY AND FLEXIBILITY TO COVER A COMPREHENSIVE RANGE OF MITRAL VALVE REPAIR NEEDS.<sup>1</sup>**

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

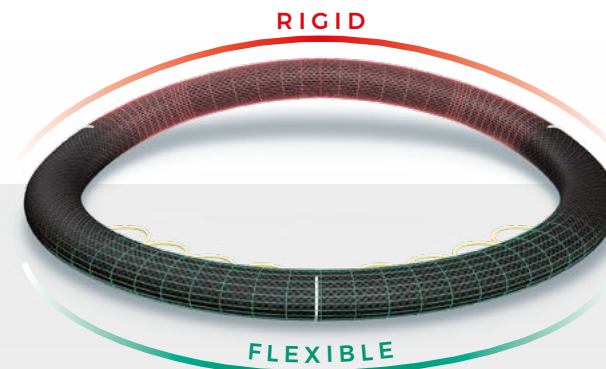


## Stability and Support

### THE RIGHT BALANCE OF RIGIDITY AND FLEXIBILITY TO COVER A COMPREHENSIVE RANGE OF MITRAL VALVE REPAIR NEEDS.<sup>1</sup>

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

### THE NATURAL ANNULAR DYNAMICS OF THE MEMO PLATFORM IS CLINICALLY PROVEN AND ACKNOWLEDGED.<sup>5,7</sup>



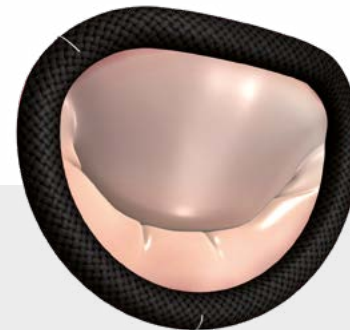
*"MEMO 3D preserves annular dynamics and folding dynamics."<sup>12</sup>*

*"MEMO 3D allows for contraction during systole, an increased depth of coaptation of the leaflets and an improvement in annular orifice area during diastole."<sup>10</sup>*

## Optimized Hemodynamics<sup>5,6,7</sup>

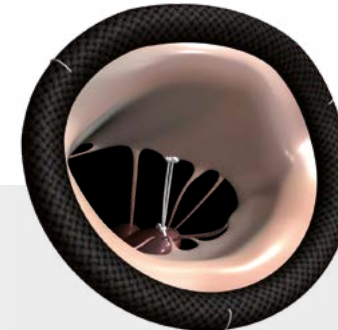
### TRULY PHYSIOLOGICAL THREE-DIMENSIONAL MOTION

of the mitral annulus with a natural anterior/posterior to lateral/lateral relationship to maximize blood flow,<sup>7</sup> even five years after implantation.<sup>5,13</sup>



#### Systolic remodelling

Maximized Coaptation  
and Reduced Stress<sup>6,7,10</sup>



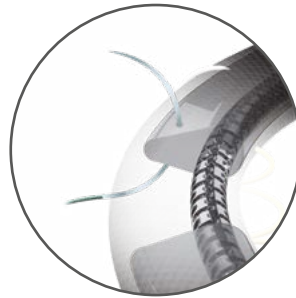
#### Diastolic dynamics

Maximized  
Hemodynamics<sup>12</sup>

*"In our study, the semi-rigid MEMO 3D annuloplasty ring was associated with a better hemodynamic at rest and during exercise and clinical status."<sup>6</sup>*

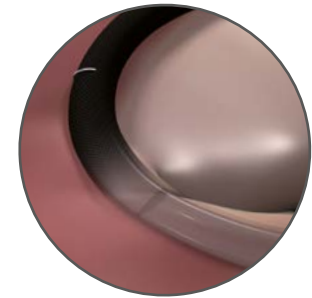
# Ease-of-Implant

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

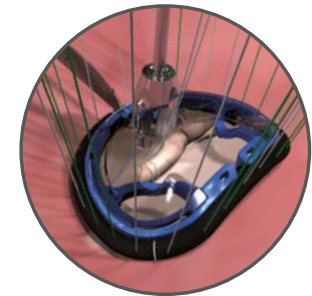


### Chordal window

Neochordae can pass  
through the aperture

### One-cut removal

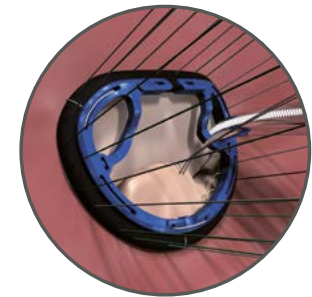
Single cut to unhook  
the whole holder



### Designed to facilitate mics approach

Low-profile holder

Ultra-slim template  
with two handles

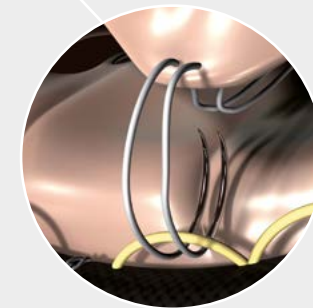
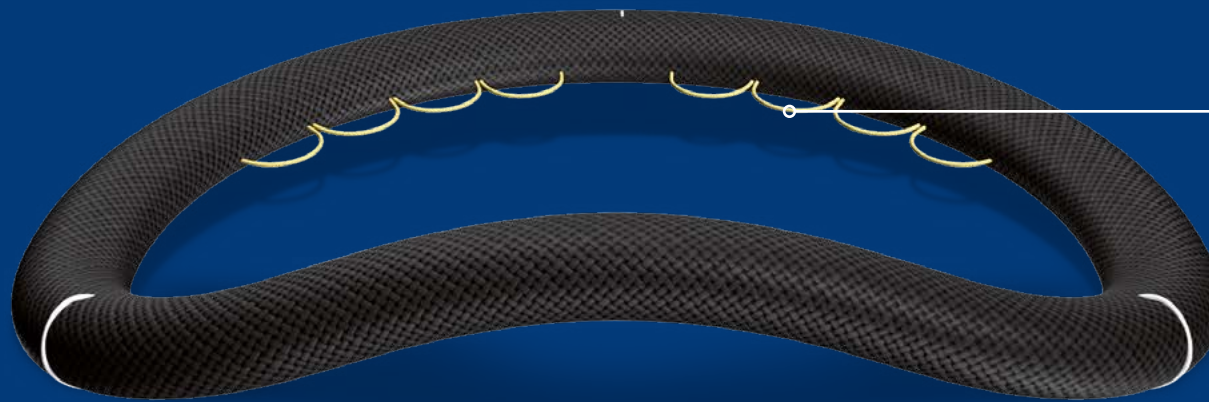




# ReChord System

**A CHORDAL SIZING SYSTEM THAT AIMS TO STANDARDIZE NEOCHORDAE IMPLANTATION WITHOUT THE NEED FOR PHYSICAL MEASUREMENT.**<sup>2,3</sup>

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.<sup>3,14</sup>



*"The chordal guiding system markedly reduces the time of the procedure by facilitating sizing and knotting."*<sup>15</sup>

## PRODUCT ORDERING INFORMATION

CODE	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



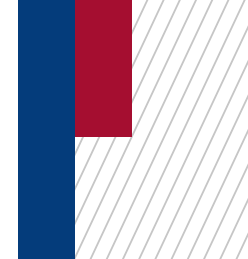
\* Inner metal core diameter

\*\* Made to order

## ACCESSORIES ORDERING INFORMATION

CODE	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





## REFERENCES

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2. Wan et al., "Mitral valve repair using a semirigid ring: patient selection and early outcomes." *Asian Cardiovascular & Thoracic Annals* 0(0):1-6 2016
3. 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 three-dimensional 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 Regurgitation." *Circulation* 2013;127:832-841
9. Adams et al., "Large Annuloplasty Rings Facilitate Mitral Valve Repair in Barlow's Disease." *Ann Thorac Surg* 2006;82:2096-101
10. 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
11. Della Barbera et al., "Sovering annuloplasty rings: Experimental pathology in the sheep model." *Cardiovascular Pathology* 14 (2005) 96-103
12. Ryomoto et al., "Is Physiologic Annular Dynamics Preserved After Mitral Valve Repair With Rigid or Semirigid Ring?" *Ann Thorac Surg* 2014;97:492-8
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 J Cardiol*. 2012 Dec 14
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

#### INTENDED USE/INDICATIONS

**EUROPE, US:** Memo 4D device is intended to reshape and support the mitral annulus after the surgical repair. The use of the Memo 4D 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 4D device is intended for correction of mitral insufficiencies or steno-insufficiencies. The use of the Memo 4D 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 Sorin Group Italia. 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. Consult your labeling.



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