

MEMO 3D[™] The true reflection of the mitral annulus

Natural physiological 3D motion

Imagine...

if there was one annuloplasty ring that provided an optimal solution across the entire spectrum of mitral valve repair.
a single ring that could provide reproducible results, predictable outcomes, and superior performance.

then imagine if that ring offered **natural physiological 3D motion** with an innovative internal cell structure, **shape memory** and a **state of the art coating** for enhanced hemo and biocompatibility to **truly reflect** the native mitral annulus.

Stop imagining.

UNIQUE FEATURES

The Right Balance of Rigidity and Flexibility to Support any Repair

Memo 3D[™] semi-rigid annuloplasty ring is truly the only ring you'll ever need. Whether you're looking for stability to support annulus remodeling - or seek flexibility to allow natural motion of the annulus, the unique features of Memo 3D[™] provide superior performance in both environments.

3D Innovative Nitinol Cell Structure

The varying dimensions of the nitinol cell structure of Memo 3D[™] allows for true physiological movement in all 3 dimensions. This helps to reduce stress on the repair by allowing the prosthesis to better accommodate the natural motion of the mitral annulus. The cell structure is optimized to provide a progressive degree of flexibility from the anterior to posterior portions of the ring.

Carbofilm[™] a LivaNova exclusive

Coated entirely with Carbofilm[™], Memo 3D[™] observed through TEE and MRI, has demonstrated its ability to preserve near phisiological ring motion after one year of implant^{1,2}. Recent clinical data showed this unique performance even after more than five years of implant³.

Unique Saddle Shape Configuration

The true physiological 3D motion of the ring during the cardiac cycle preserves the natural non-planar geometry saddle shape 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 implantation⁷.









Carbofilm magnified to show texture





4D MV assessment and Realview analysis: annular height changes during the cardiac cycle being highest in mid-systole and lowest in mid-diastole⁷. Saddle shape remodeling contributes to increased repair durability by redistributing leaflet stress and chordal tension ^{4,5,6}.

✓ The LivaNova Memo 3D[™] ring safely and effectively minimizes secondary MVR resulting from all causes and preserves mitral annular flexibility and function at follow-up². 99

AN OPTIMAL SOLUTION ACROSS THE ENTIRE SPECTRUM OF VALVE REPAIR

Shape Memory

The Ni-Ti alloy core "remembers" a prefixed shape after geometric deformation and can be flexed back and forth without losing its original form. Memo 3D's shape memory provides consistent recovery of the systolic profile and restores the natural systolic diameter ratio.



VERSATILITY

Memo 3D[™] has been successfully implanted in patients presenting a broad range of etiology classifications with applications in both degenerative and ischemic disease.

BRUNO ET AL. ²	ETIOLOGY	N°	%
63 patients,	Degenerative	39	61.9
mean age 70 years,	Ischemic	16	25.4
76% NYHA Class III-IV,	Barlow's Disease	4	6.4
24% NYHA Class I-II	Dilated		
	Cardiomyopathy	4	6.4

REIN ET AL.º	ETIOLOGY	N°	9	6
125 patients,	Degenerative	69	55	5.2
mean age of 66 years,	Ischemic	19	15	5.2
79% NYHA Class III-IV,	Congenital	5	4	l.0
14% NYHA Class I-II,	Rheumatic	8	6	6.4
7% undefined	Endocarditis	6	4	.8
	Barlow's Disease	5	4	l.0
	Other	13	10).4
SORIN CLINICAL TRIAL ⁹	ETIOLOGY		N°	%
SORIN CLINICAL TRIAL ⁹ 228 patients,	ETIOLOGY Degenerative		<mark>N°</mark> 172	% 75.4
SORIN CLINICAL TRIAL ⁹ 228 patients, mean age 63 years,	ETIOLOGY Degenerative Ischemic		N° 172 42	% 75.4 18.5
SORIN CLINICAL TRIAL ⁹ 228 patients, mean age 63 years, 39% NYHA Class III-IV,	ETIOLOGY Degenerative Ischemic Dilated Cardiomiop	athy	N° 172 42 11	% 75.4 18.5 25.0
SORIN CLINICAL TRIAL ⁹ 228 patients, mean age 63 years, 39% NYHA Class III-IV, 61% NYHA Class I-II	ETIOLOGY Degenerative Ischemic Dilated Cardiomiop Endocarditis	athy	N° 172 42 11 7	% 75.4 18.5 25.0 3.1
SORIN CLINICAL TRIAL ⁹ 228 patients, mean age 63 years, 39% NYHA Class III-IV, 61% NYHA Class I-II	ETIOLOGY Degenerative Ischemic Dilated Cardiomiop Endocarditis Rheumatic	athy	N° 172 42 11 7 7	% 75.4 18.5 25.0 3.1 3.1

EASE OF IMPLANT

Ensuring a better fit

The Memo 3D[™] semirigid annuloplasty ring facilitates easier implantation with superior visualization, placement, and attachment. The oval cross section of the silicone sheath provides more material for easier needle penetration. White suture guidelines on the underside of Memo 3D[™] provide an excellent visual reference point for easier suturing.



NOW with improved HOLDER

Compatible with new set of accessories designed also for MICS

NEW HOLDER:

- Compatibility with new improved set of accessories, suitable also for MICS procedures
- Versatility of use:
- one-step or two-step procedures for removal



WARNING



NOT TO BE USED WITH HANDLE RG-100

Use exclusively with the new ICV0664 Uni Handle or ICV1342 Extended Uni Handle for MICS

NEW ACCESSORIES:

- Longer version of the universal bendable handle for MICS
- Improved ergonomic sizers
- Sizer heads with marked size for easy recognition
- Printed commissural markers to avoid annular suture entangling



Product ordering information

Memo 3D[™] semirigid annuloplasty ring: Ni-Ti Alloy core covered by silicone and polyester fabric coated with Carbofilm[™]

Ordering Number	Size	A (mm)	Orifice area (cm²)
ICV0966	24	24	2.30
ICV0967	26	26	2.78
ICV0968	28	28	3.28
ICV0969	30	30	3.78
ICV0970	32	32	4.39
ICV0971	34	34	4.98
ICV0972	36	36	5.67
ICV0973	38	38	6.34



Accessories ordering information (not provided sterile)

	Catalog Number	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
1.1			

References

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- 3. 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!" Department of Cardiac Surgery, Klinikum Nürnberg, Nuremberg, Germany. (abstract). Int J Cardiol. 2012 Aug 23;159(2):e23-4.
- 4. Salgo IS. et al. "Effect of Annular Shape on Leaflet Curvature in Reducing Mitral Leaflet Stress." Circulation. 2002;106:711-717.
- 5. Gorman JH. et al. "Effect of regional ischemia on mitral valve annular saddle shape and function." Ann Thorac Surg. 2004;77:544-8.
- 6. Jimenez JH. et al. "Effects of a saddle shaped annulus on mitral valve function and chordal force distribution: An in vitro Study." Annals of Biomedical Engineering. 2003;31:1171-1181.
- 7. Nishi H. et al. "Real-time 3-dimensional transesophageal echocardiography enable the evaluation of annular dynamics of mitral valve repair." Department of Cardiovascular Surgery, Osaka University Graduate School of Medicine, Osaka, Japan. Society of Heart Valve Disease (Abstract). Venice, 2013.
- 8. Rein et al. Sana Cardiac Surgical Clinic, Stuttgart, Germany. Institute Data, 2007.
- 9. Sorin Group. Multicentre Prospective Clinical Trial Interim Analysis. Internal Data. March 2011.



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Please always refer to the Instructions For Use (IFU) manual provided with each product for detailed information, warnings, precautions and possible adverse side effects.

