ANNULOPLASTY
RING

SOVERING™

The flexible solution
to annuloplasty rings

CORCYM
WE TAKE LIFE TO HEART

SOVERING™

SOVERING MITRAL RING	SOVERING MITRAL BAND	SOVERING TRICUSPID BAND

SOVERING™ ANNULOPLASTY RINGS ARE FLEXIBLE DEVICES MADE OF:

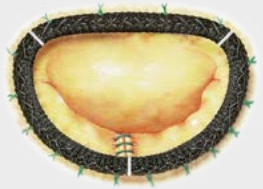
- Radiopaque silicone core
- Knitted polyester (PET) fabric, coated with Carbofilm™

Enhanced* bio-hemocompatibility and compactness[1,2]

- Carbofilm coating enhances biocompatibility and hemocompatibility and minimizes fibrous overgrowth.*[1,2]

- One piece construction (silicone/PET fabric) avoids displacement between the silicone core and the outer fabric when suturing, ensuring compactness.
- The flexibility of the core has been designed to allow the natural 3D motion of the annulus during the cardiac cycle.[3]
  Flexibility reduces the stress on the sutures, minimizing the likelihood of dehiscence.**

- Silicone core impregnated with Barium sulfate enables radiographic visualisation.
- White markers facilitate commissural alignment and device seating.



* Compared to non-Carbofilm coated rings.

** Based on LivaNova post-market surveillance, dehiscence is expected to occur less than 1 time per 1000000 device population.

1. *Della Barbera et al., Sovering annuloplasty rings: Experimental pathology in the sheep model, Cardiovascular Pathology 14 (2005) 96- 103.*
2. *Sbarbati et al., Pyroliytic carbon coating enhances Teflon and Dacron fabric compatibility with endothelial cell growth, The International Journal of Artificial Organs/Vol. 14 /no. s, 1991 /pp. 491-498.*
3. *Dagum et al., Three-dimensional geometric comparison of partial and complete flexible mitral annuloplasty rings, J Thrac Cardiovasc Surg 2001:122:665-73.*

Technical claims are supported by CORCYM data on file.

AVAILABLE MODELS

CORCYM provides Surgeons with two mitral models and one tricuspid model.

- Sovering Mitral Ring
- Sovering Mitral Band
- Sovering Tricuspid Band

SURGICAL CONSIDERATIONS

Designed for easy implantability

- Rings/Bands are pre-mounted on a holder composed of two parts. The clutch, designed for a safe connection with the UNI Handle, is sutured to a template which mimics the shape of the mitral and tricuspid annuli.

Surgeons may choose:

- To remove the holder (clutch+template) after suturing.
- To remove first the clutch maintaining the template in place for proper suturing without distortion then the template.
- Ring/Band selection is based on the measurement of the intercommissural distance and matching of the same to the notches on the sizer.
- Ring/Band selection may also be based on the measurement of the anterior leaflet area with the same sizer.

PRACTICAL PACKAGING

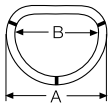
Each mitral and tricuspid Sovering annuloplasty system box contains:

One ring (or band), pre-mounted on a holder.

Technical claims are supported by CORCYM data on file.

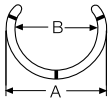
PRODUCT ORDERING SPECIFICATIONS

SOVERING MITRAL RING



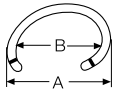
REF	Ordering Number	SIZE	Lenght* (mm)	External* diameter A (mm)	Interrnal* diameter B (mm)
SA26M	ICV0839	26	-	31.2	25.2
SA28M	ICV0840	28	-	33.2	27.2
SA30M	ICV0841	30	-	35.2	29.2
SA32M	ICV0842	32	-	37.2	31.2
SA34M	ICV0843	34	-	39.2	33.2
SA36M	ICV0844	36	-	41.2	35.2
SA38M	ICV0845	38	-	43.2	37.2
SA40M	ICV0846	40	-	45.2	39.2

SOVERING MITRAL BAND



REF	Ordering Number	SIZE	Lenght* (mm)	External* diameter A (mm)	Interrnal* diameter B (mm)
SB26M	ICV0826	26	60	31.2	25.2
SB28M	ICV0827	28	64	33.2	27.2
SB30M	ICV0828	30	68	35.2	29.2
SB32M	ICV0829	32	72	37.2	31.2
SB34M	ICV0830	34	76	39.2	33.2
SB36M	ICV0831	36	80	41.2	35.2
SB38M	ICV0832	38	84	43.2	37.2
SB40M	ICV0833	40	88	45.2	39.2

SOVERING TRICUSPID BAND



REF	Ordering Number	SIZE	Lenght* (mm)	External* diameter A (mm)	Interrnal* diameter B (mm)
SB28T	ICV0834	28	64	33.8	27.8
SB30T	ICV0835	30	68	35.8	29.8
SB32T	ICV0836	32	72	37.8	31.8
SB34T	ICV0837	34	76	39.8	33.8
SB36T	ICV0838	36	80	41.8	35.8

* Nominal dimensions

ACCESSORIES ORDERING INFORMATION (not provided sterile)

Ordering Number	Name	Description
ICV0664	UNI Handle	Bendable handle for **rings, band and sizers**

Ordering Number	Name	Description
ICV0824	Sizer set	Sizer set for **Sovering Mitral Ring** and **Sovering Mitral Band**

Ordering Number	Name	Description
ICV0825	Sizer set	Sizer set for **Sovering Tricuspid Band**

INTENDED USE/INDICATIONS
Sovering annuloplasty device is indicated to support the mitral or the tricuspid annulus after the surgical repair. The Sovering Mitral Ring and Mitral Band are indicated for congenital or acquired mitral valve insufficiencies characterised by the dilatation or deformation of the native annulus. The Sovering Tricuspid Band is indicated for acquired tricuspid valve insufficiency, both organic and functional. The Sovering Miniband is indicated for posterior mitral annuloplasty, in accordance with valve orifice "over-reduction" application techniques.

KEY CONTRAINDICATIONS
The annuloplasty rings should not be used in the case of: extensive organic lesions with retraction of the chordae, congenital malformations with scarce/nonexistent valvular tissue, massy calcification of valve leaflets, evolving bacterial endocarditis.

KEY WARNINGS
The Sovering device is intended for single use only. Do not attempt to clean, resterilize, or reuse any prosthesis. Use only accessories supplied by Corcym for implanting the device. The correct measurement of the annulus is essential. Use only the sizers supplied by Corcym.

TOP POTENTIAL SIDE EFFECTS
A number of complications, sometimes fatal, are associated with the use of annuloplasty devices. The complications most frequently associated with the use of annuloplasty devices include: residual or recurrent regurgitation insufficiency; stenosis; thrombosis and embolism; hemolysis; atrioventricular block leading to temporary pacing; low cardiac output syndrome; ventricular heart failure; valve malfunction due to the progression of the pathological condition, endocarditis, incomplete/inadequate correction; occlusion of circumflex artery due to surgical suturing; partial/total detachment of device (dehiscence); laceration of device fabric due to the use of cutting edge needles; hemorrhage from the use of anticoagulants; systolic anterior motion and left ventricular outflow tract obstruction; complications related to prolonged ECC time. Complications related to individual patient reaction to the prosthesis implant or physical/chemical changes in the components may also occur, requiring re-operation and the replacement of the prosthesis..

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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WE TAKE LIFE TO HEART

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