MEMO 3D RECHORD™
Ready to repair

Designed to standardize mitral repair
CAR DiAC SuRGERY SOlUTIONS
A 45-year long history of innovative records in cardiac surgery

LivaNova’s relentless commitment to providing innovative solutions through advanced technologies and breakthrough therapeutic treatments for cardiovascular diseases is an innate trait of its DNA and has brought the company to become world leader in the field of cardiac surgery.
LivaNova offers a portfolio of solutions to all types of mitral valve disease

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

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

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.
MITRAL SOLUTIONS

“Mitral valve repair is now the most frequently performed surgical procedure for mitral valve disease…but repair and replacement may be applied to different subsets of patients.”

Each patient requires a tailored care, and every surgeon needs in his hands the best solution to meet this expectation. Therefore to address the surgical need to have the best solution fitting each patient and surgeon requirements, only a truly integrated offering can respond. LivaNova Mitral Solutions offers a full range of devices for each and every need: flexible, rigid and semirigid annuloplasty rings for mitral repair and both biological and mechanical prostheses for mitral valve replacement.

Innovation rings true
Introducing Memo 3D

LivaNova 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 mimic 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 LivaNova post-market surveillance, ring-related mitral regurgitation is expected to occur between 1 and 10 times per 10000 device population.

DESIGN
Unique to its core
Unique super-elastic alloy core

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 LivaNova’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.

The right balance of rigidity and flexibility to support both degenerative and functional mitral repair

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.

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.

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.

Technical claims are supported by LivaNova data on file.
PERFORMANCE

The reflection of the mitral annulus
Systolic remodeling and diastolic dynamics concept

Truly three-dimensional motion of the mitral annulus with a 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 stress\(^1\)

**Diastolic dynamics**

optimized hemodynamics\(^2\)

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.\(^3,4,5\)

---

IMPLANTATION

Ease of use and implant

Technical claims are supported by LivaNova data on file.
**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.

Technical claims are supported by LivaNova data on file.
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.¹²

* Based on LivaNova post-market surveillance, ring-related mitral regurgitation is expected to occur between 1 and 10 times per 10,000 device population.

Guiding Standards

Facilitating and standardizing the implantation procedure.¹

2. Wan et al., Mitral valve repair using a semi-rigid 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

Mitral regurgitation: chordal rupture
Anchoring of the artificial chord
Chord should be passed through the window
Ring parachuting and implantation
Cut at the P2 area and remove the holder
Implantation procedure

Knots are tied at the annular level.

Tie the knots tight.

Step 1: pull the blue thread first
Step 2: then pull the yellow thread.

Knots are tied at the annular level.

Truly 3D motion of the mitral annulus.

Fast and simplified procedures for desirable patient outcomes.

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

5. 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.
Holder

One-step removal

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

1. Cut and remove the holder
2. Tie the knots tight

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.

1. Cut
2. Cut
3. Cut at the P2 area and remove the template with forceps
2. Tie the knots tight
Clinical highlights from the first published experience

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

“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.”

“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.”

Product ordering information

Memo 3D ReChord semirigid annuloplasty ring: superelastic alloy core covered by silicone and polyester fabric coated with Carbofilm

<table>
<thead>
<tr>
<th>Ordering Number</th>
<th>Size</th>
<th>A (mm)</th>
<th>Orifice area (cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICV1330</td>
<td>24</td>
<td>24</td>
<td>2.30</td>
</tr>
<tr>
<td>ICV1331</td>
<td>26</td>
<td>26</td>
<td>2.78</td>
</tr>
<tr>
<td>ICV1332</td>
<td>28</td>
<td>28</td>
<td>3.28</td>
</tr>
<tr>
<td>ICV1333</td>
<td>30</td>
<td>30</td>
<td>3.78</td>
</tr>
<tr>
<td>ICV1334</td>
<td>32</td>
<td>32</td>
<td>4.39</td>
</tr>
<tr>
<td>ICV1335</td>
<td>34</td>
<td>34</td>
<td>4.98</td>
</tr>
<tr>
<td>ICV1336</td>
<td>36</td>
<td>36</td>
<td>5.67</td>
</tr>
<tr>
<td>ICV1337</td>
<td>38</td>
<td>38</td>
<td>6.34</td>
</tr>
</tbody>
</table>

Accessories ordering information (not provided sterile)

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICV0664</td>
<td>Uni Handle</td>
<td>Universal Bendable Handle</td>
</tr>
<tr>
<td>ICV1342</td>
<td>Extended Uni Handle</td>
<td>Universal Bendable Handle for MICS</td>
</tr>
<tr>
<td>ICV1340</td>
<td>Annuloplasty Ring Sizer Set</td>
<td>Complete Sizer Set (24 to 38 mm)</td>
</tr>
<tr>
<td>ICV1343</td>
<td>Annuloplasty Ring Accessory Tray</td>
<td>Empty Instrument Tray</td>
</tr>
</tbody>
</table>
INDICATIONS:
EUROPE and US: The Memo 3D ReChord annuloplasty ring is intended for correction of mitral insufficiencies, steno-insufficiencies or acquired mitral insufficiencies (type I, type II, type III) with dilatation and deformation of the mitral annulus. The decision to undertake a mitral valve repair must remain with the surgeon after having evaluated short- and long-terms risks and benefits towards alternative procedures and on the visual inspection of the lesion in the individual case.

TOP POTENTIAL SIDE EFFECTS:
The use of prosthetic annuloplasty rings is associated with serious potential complications, which include: death, reoperation and explants, residual or recurrent regurgitation, stenosis, thromboembolism, hemolysis, atrio-ventricular block, endocarditis, low cardiac output, failure or degeneration of the natural valvular apparatus due to progression of disease, partial/total ring dehiscence, 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, systolic anterior motion (SAM) and left ventricular outflow tract obstruction (LVOTO), prosthesis thrombosis, infection.

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.

MRI conditional. For professional use. Please contact us through our website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Consult your labeling.