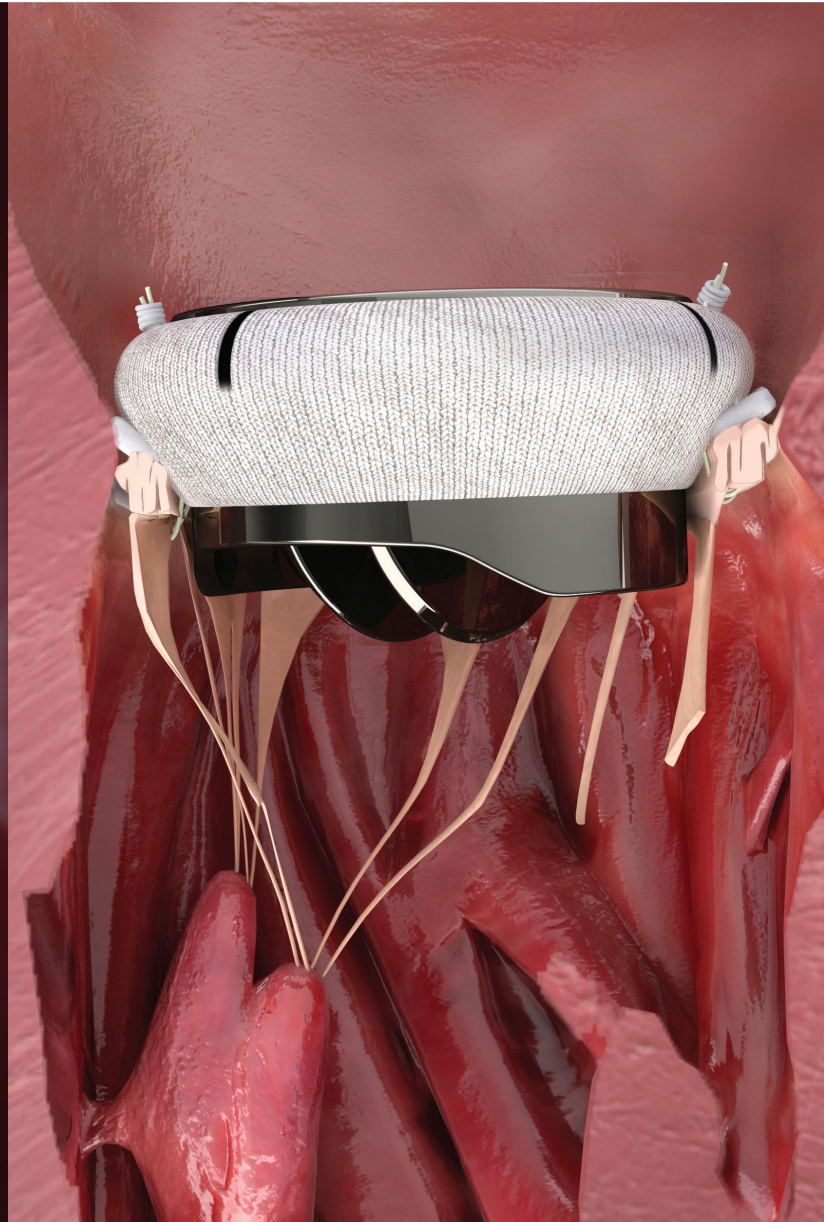
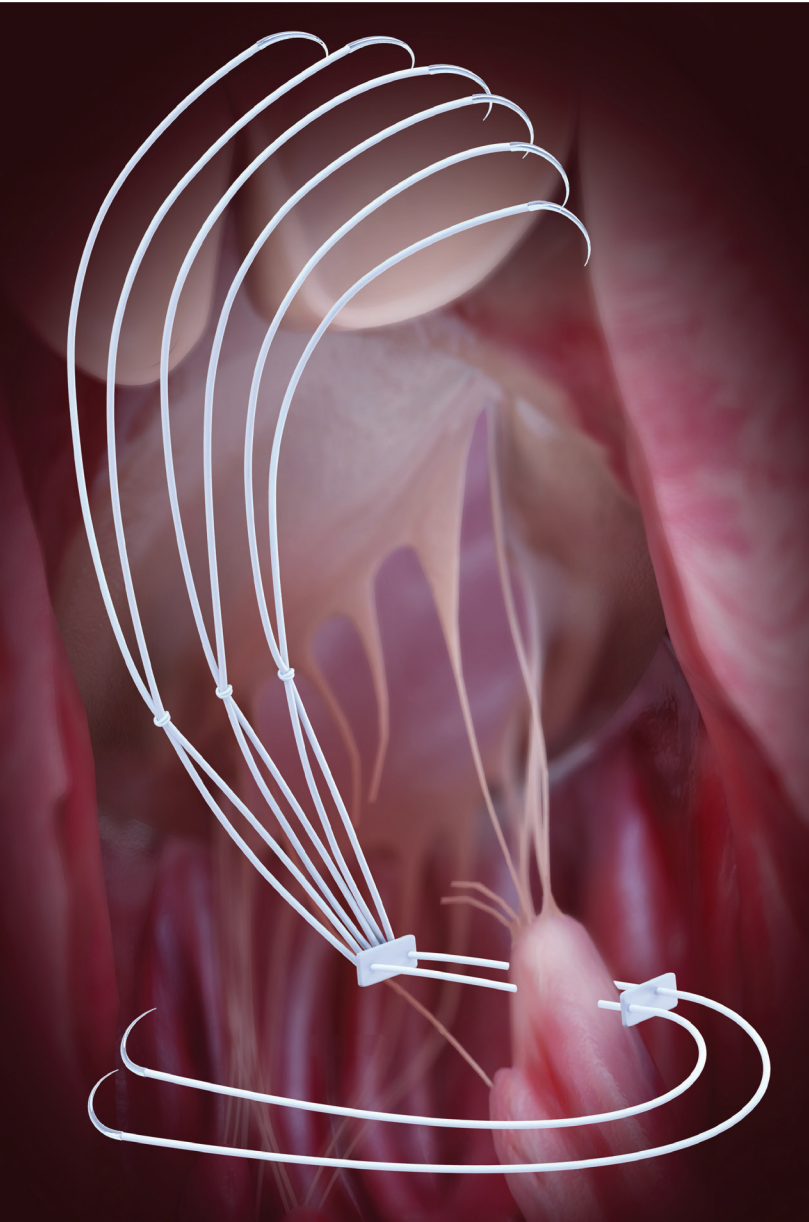


Mitral Valve Solutions

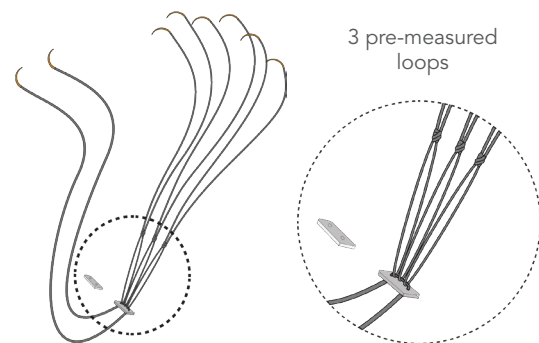
Chord-X® Mitral Chordal Replacement Products

On-X® Mitral Heart Valves



CryoLife[®]
Life Restoring Technologies[®]

For Mitral Valve Repair

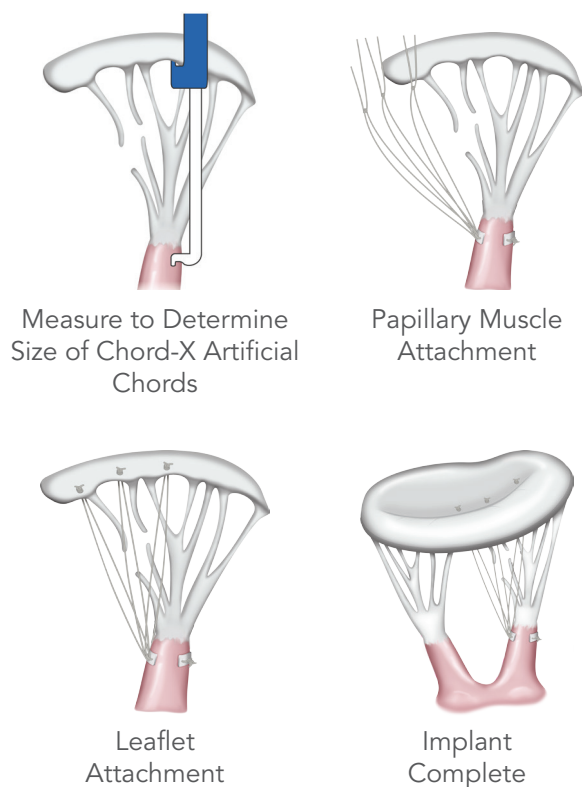


Chord-X is an innovative tool for mitral valve repair, and is designed to:

- Save time*
- Allow reproducible results
- Simplify mitral valve repair procedures

*Compared to artificial chords made by surgeon.

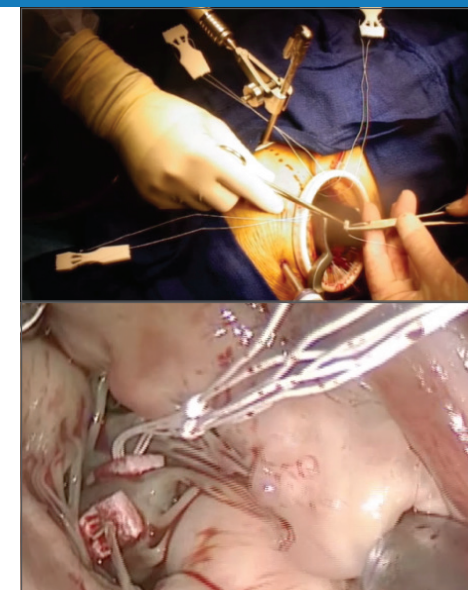
Procedural Overview



See Instructions for Use for full details.²

Mitral Valve Repair

- Mitral valve repair is strongly preferred over replacement for primary MR whenever anatomically feasible.¹
- Short- and long-term outcomes of successful valve repair for primary MR exceed those for valve replacement across all age ranges.²
- Chordal replacement may be associated with greater freedom from reoperation and may lead to improved postoperative left ventricular function compared with leaflet resection.³
- Chordal implantation keeps the door open for further treatments in case of MR recurrence.⁴



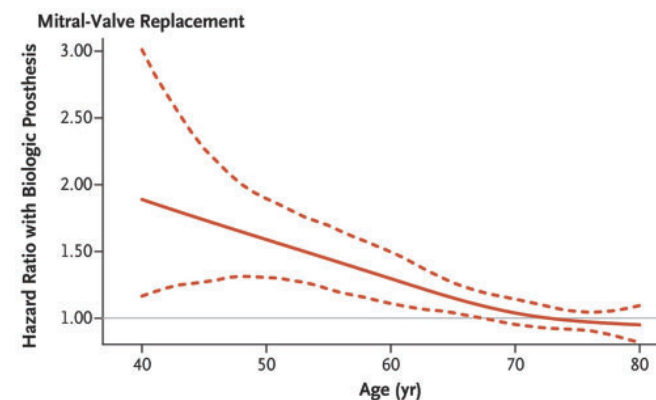
Chord-X Pre-Measured Loops provide an innovative solution to simplify and standardize mitral valve repair.

If mitral valve repair is not possible, consider your options for mitral valve replacement

Mitral Valve Replacement

Advantages of Mechanical Valves:

- "...mechanical valve prostheses remain the gold standard for valve replacement in younger individuals" when mitral valve repair is not possible.⁵
- Mechanical mitral valve offers survival benefit at 15 years for patients <70⁶ (see graph below)



Disadvantages of Tissue Valves:

- Calcification of leaflets increase valve gradients until reoperation is required⁶
- No guarantee patient will not need long term anticoagulation⁷
- 3-4 times more likely to require reoperation when compared to mechanical valves⁶
 - o Note: 30-day mortality for all reoperative mitral valve replacement is 14%⁶

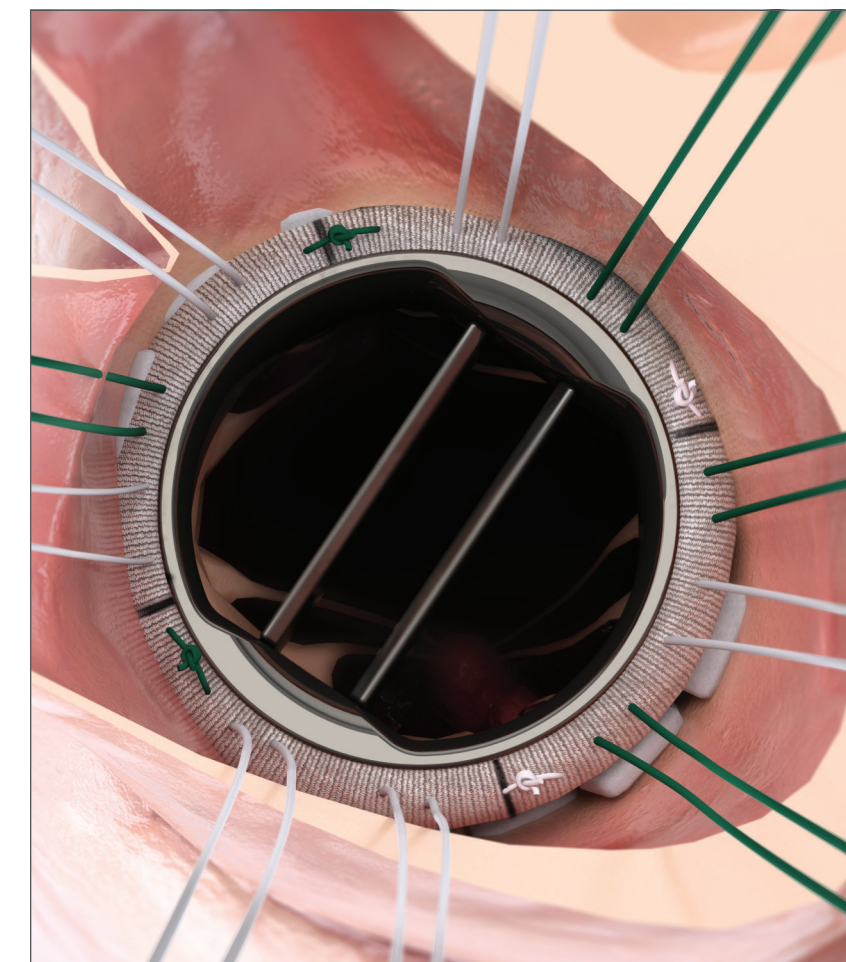
The On-X Mitral Valve offers the "gold standard" solution for mitral valve replacement.⁵

For Mitral Valve Replacement



- Pure pyrolytic carbon for reduced thrombogenicity⁸
- < 4.4 mm Hg across all valve sizes 25 – 33 mm⁹
- Sewing cuff designs made from polytetrafluoroethylene (PTFE)⁹
- Leaflet guards designed to prevent encroachment of subvalvular apparatus

90° Leaflet Opening



Ordering Information

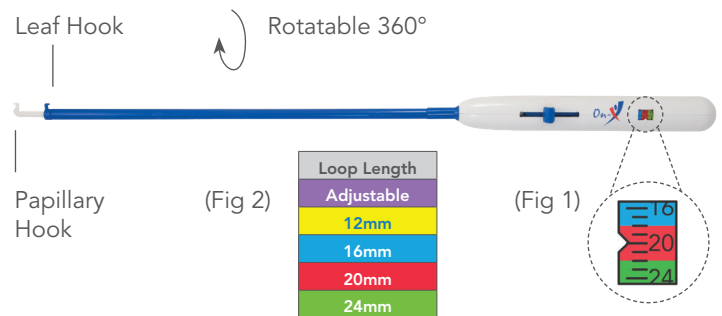
Chord-X Pre-Measured Loops and Adjustable Suture System

| ePTFE Suture Diameter: USP 2-0 (Diameter similar to GORE-TEX® CV-4) | 18mm Taper Point Needle Options, Catalog Numbers | |
|---|---|----------------|
| Loop Length | 3/8 Circle | 1/2 Circle |
| Adjustable | CXL-20-1838-0 | CXL-20-1812-0 |
| 12mm | CXL-20-1838-12 | CXL-20-1812-12 |
| 16mm | CXL-20-1838-16 | CXL-20-1812-16 |
| 20mm | CXL-20-1838-20 | CXL-20-1812-20 |
| 24mm | CXL-20-1838-24 | CXL-20-1812-24 |

- 1 box = 5 sterile Chord-X packaged units.
- Each unit contains a Chord-X prosthesis featuring one suture pair for the papillary muscle and three independent pre-measured chordal suture loops or suture strands for leaflet attachment.
- Each prosthesis is positioned on disposable foam base-plates for suture management.
- Each unit has double-armed taper point needles, two PTFE pledgets: one attached and one independent.

Chord-X Chordal Sizer

| Packaged Quantity | Use | Catalog Number |
|--|-------------------------------|----------------|
| 1 box = 5 individually packaged sterile Chord-X Chordal Sizers | Single use, disposable device | CXCS |



On-X Mitral Valve Standard Sewing Cuff



| Valve Size | Product Code |
|------------|--------------|
| 23* | ONXM-23 |
| 25 | ONXM-25 |
| 27/29 | ONXM-27/29 |
| 31/33 | ONXM-31/33 |

On-X Mitral Valve Conform-X Sewing Cuff



| Valve Size | Product Code |
|------------|--------------|
| 25/33 | ONXMC-25/33 |

Learn more at: www.CryoLife.com

1. Nishimura RA, Otto CM, Bonow RO, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2014;63:2438-88.

2. Vassileva CM, Mishkel G, McNeely C, et al. Long term survival of patients undergoing mitral valve repair and replacement: a longitudinal analysis of Medicare fee-for-service beneficiaries. Circulation. 2013;127: 1870-6.

3. J Thorac Cardiovasc Surg. 2018 Jan;155(1):120-128.e10. doi: 10.1016/j.jtcvs.2017.07.078. Epub 2017 Aug 24. Systematic review and meta-analysis of chordal replacement versus leaflet resection for posterior mitral leaflet prolapse.

4. Milind Y, Desai, Francesco Grigioni, Marco Di Eusanio, Matteo Saccoci, Maurizio Taramasso, Francesco Maisano, Rakesh M. Suri, A. Marc Gillinov. Outcomes in Degenerative Mitral Regurgitation: Current State-of-the Art and Future Directions. Progress In Cardiovascular Diseases 60 (2017) 370-385

5. Chiu P, Goldstone AB, Woo YJ. Eur J Cardiothorac Surg 2018;54:622-6.

6. Goldstone AB et al. N Engl J Med 2017;377:1847-1857

7. Nishimura et al., Circulation. 2017;135:e1159-e1195.

8. LaGrange L et al., Compatibility of carbon and blood. Hegyeli RJ, Editor, Proceedings, Artificial Heart Program Conference, Washington, DC, June 9-13, 1969, 47-58.

9. On-X Prosthetic Heart Valve Instructions for Use.

On-X Life Technologies, Inc. is a wholly owned subsidiary of CryoLife, Inc. The On-X Prosthetic Heart Valves and Mitral Chordal Replacement Products are manufactured by On-X Life Technologies, Inc. CryoLife, the snowflake design, Life Restoring Technologies, On-X and Chord-X are registered trademarks owned by CryoLife, Inc. or its subsidiaries. All other registered trademarks are owned by their respective owners. © 2018 CryoLife, Inc. All rights reserved. Surgical technique is at the discretion of the surgeon. Variations in technique and practices will inevitably and appropriately occur when clinicians take into account the needs of the individual patients, available resources, and limitations unique to an institution or type of practice.

On-X Life Technologies, Inc.
1300 East Anderson Lane, Bldg. B
Austin, Texas 78752 USA
Phone: (512) 339-8000
Fax: (512) 339-3636
Email: onx@onxlti.com

CryoLife, Inc.
1655 Roberts Boulevard, NW,
Kennesaw, Georgia 30144 USA
Phone: 888-427-9654
Fax: 770-590-3753
Email: CUSTSVC@cryolife.com

MLENG0000.000 (2018-12)

 **CryoLife**
Life Restoring Technologies