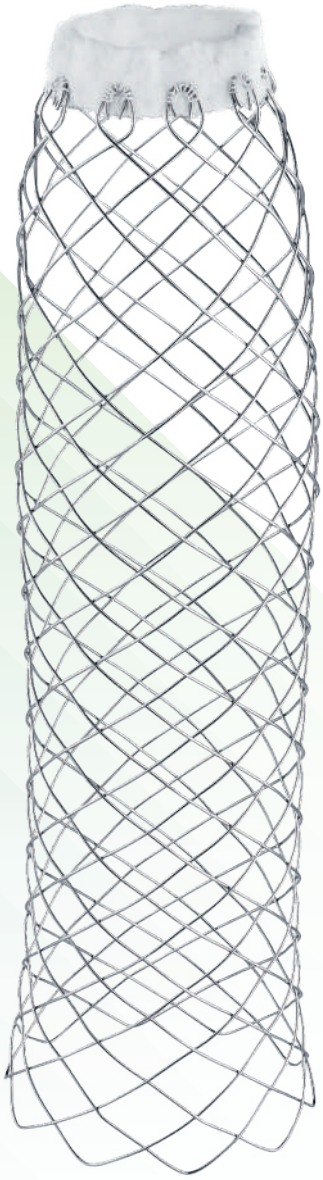
# Elevate the Standard.
# Rethink Prevention.

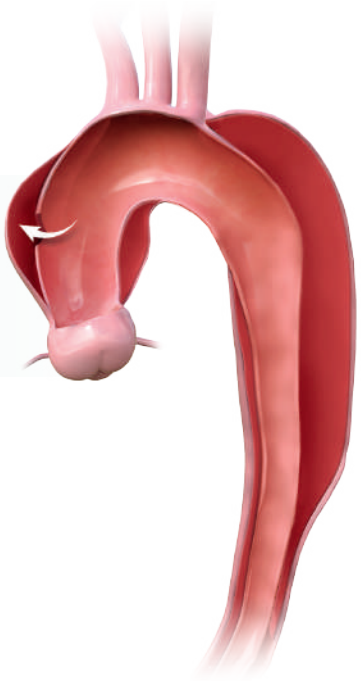


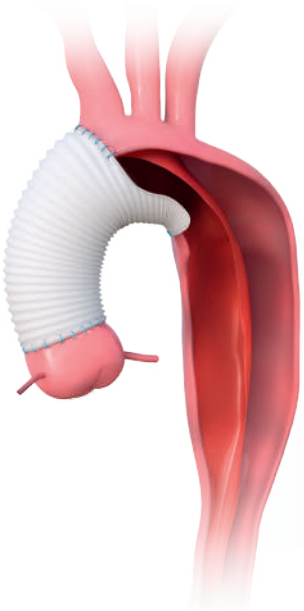
ARTIVION™ | AMDS™
Hybrid Prosthesis

# Today's Standard Treatment for Acute Type A Aortic Dissection Isn't Enough.

Type A Aortic Dissection (TAAD) presents itself emergently. Left untreated, mortality of type A dissection is reported to be approximately 1% to 2% per hour after onset of symptoms[1] and can lead to 50% mortality in the first 48 hours.[2]

Approximately 70% of entry tears occur in the ascending area.[3] Surgical repair remains high-risk, with both mortality and neurological complication rates of 15% to 30%.[1]





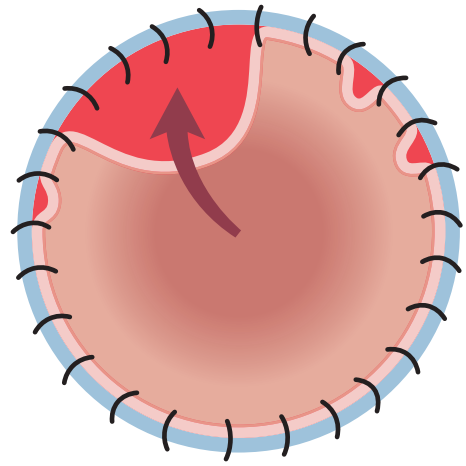
Aortic dissection is complex and difficult to treat.[4,5] Hemiarch repair alone isn't enough to stop a dissection from causing significant complications[4-7] including:

- High Mortality[5,8] + Re-intervention[6,8]
- Aortic Growth[6,9]
- Malperfusion[4,6]

**Elevate the Standard. Rethink Prevention.**

# Consider the Implications of Distal Anastomotic New Entry (DANE) following a Standard Repair for Acute TAAD.

Distal anastomotic new entry (DANE) in the standard hemiarch repair for TAAD is considered to be one of the causes of patent false lumen (PFL) after acute type I aortic dissection repair.[9-12] DANE is observed in 40-70% of patients post hemiarch repair.[6,10]



## An untreated DANE can lead to:

### High Mortality

Survival with a patent false lumen gets significantly worse over the years, with a reduced actuarial survival by over 10% at 5 years and over 30% at 10 years compared to patients with occluded false lumen.[11]

### Aortic Growth

A patent false lumen with DANE is associated with significantly greater aortic growth compared not only to a thrombosed false lumen, but also patent false lumen without DANE.[9]

### Malperfusion

Between 30-55% of all acute TAAD patients present with malperfusion.[4,13,14] In-hospital mortality rate can be 5X higher in patients presenting with any malperfusion vs. patients presenting without malperfusion.[13] At least 25% of patients have post-operative malperfusion syndrome.[4]

# A Simple Elegant Solution to Address DANE.

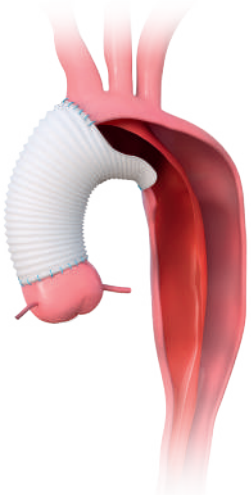
**PTFE felt graft** component made of a PTFE felt tube is used to buttress and strengthen the aortic tissue in preparation to perform the conventional polyester graft to aorta anastomosis.[15]

**Uncovered nitinol wire braided stent** enables the stabilization of the dissection flap within the aortic arch and descending aorta thereby stabilizing the structure of the aortic wall and promoting healing of the wall.[15,16]

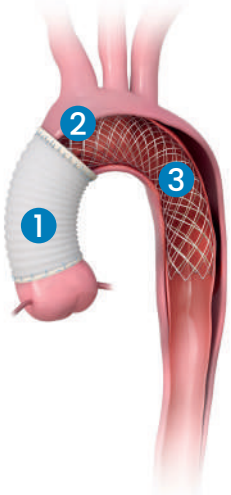
The AMDS device comes **pre-mounted on a delivery system**. There is no need for X-Ray, fluoroscopy or hybrid room to use the AMDS system.[15]

## The AMDS Hybrid Prosthesis Simply Elevates the Standard of Care for Acute TAAD

### Hemiarch Repair



### Surgical Repair + AMDS




1. Replace the ascending aorta
2. Seal the distal anastomotic entry tear (DANE)[16]
3. Stabilize the true lumen[16]

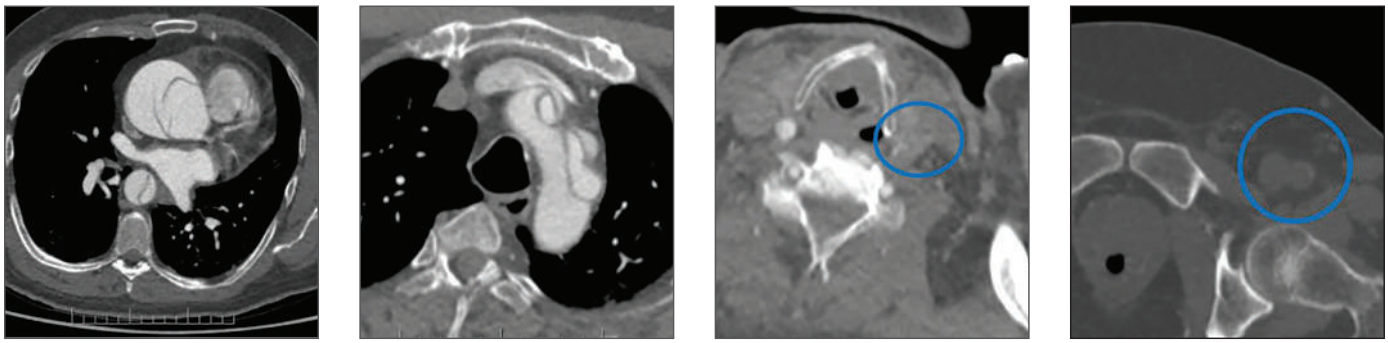
Induce Remodeling[6,9,12]

# Comparison of Standard Surgical Repair vs. Surgical Repair with AMDS.

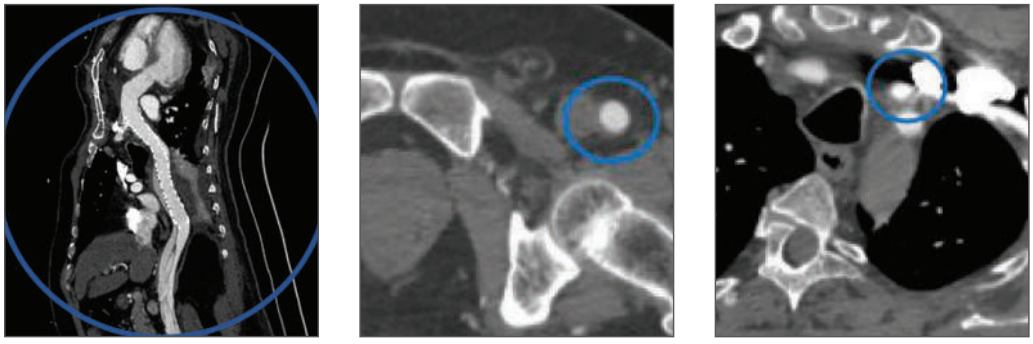
| | Standard Surgical Repair | Surgical Repair with AMDS[16] |
|---|---|---|
| Pre-Op Malperfusion | 33.6%[14] - 55.6%[4] | 56.5% |
| Overall Operative Mortality | 17%[17] - 18.7%[18] | 13.0% |
| Malperfusion Related Mortality | 21.3%[14] - 47.3%[4] | 7.7% |
| One-Stage Malperfusion Resolution | 58.1%[19] | 95.5% |
| Paralysis | 2.9%[17] | 0% |
| New Post-Op Stroke | 12.9%[20] - 13.6%[18] | 6.5% |
| Aortic Arch Remodeling (Absence of Aortic Expansion) | 24%[6] | 100% |

## Case Example

Pre-operative images of dissection and malperfusion of left common carotid and common femoral arteries

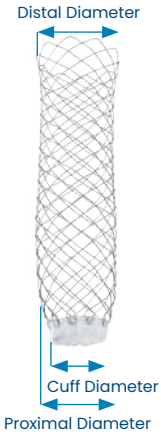


Remodeling and complete resolution of malperfusion post AMDS implantation



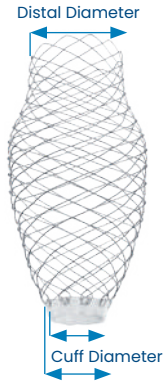
# Sizes and Configuration

## Straight




| Item | Ø Stent (mm) | Ø Proximal Aortic (mm) | Ø Distal Aortic (mm) | Device Length (mm) | Ø Felt Cuff (mm) |
|---|---|---|---|---|---|
| AMDS 40-40 | 40 | 20-35 | 25-35 | 155-208 | 24 |
| AMDS 55-55 | 55 | 36-45 | 36-45 | 195-231 | 32 |

## Tapered




| Item | Ø Stent (mm) | Ø Proximal Aortic (mm) | Ø Distal Aortic (mm) | Device Length (mm) | Ø Felt Cuff (mm) |
|---|---|---|---|---|---|
| AMDS 40-30 | 40 prox.<br>30 dist. | 20-35 | 20-24 | 170-210 | 24 |
| AMDS 55-40 | 55 prox.<br>40 dist. | 36-45 | 27-35 | 190-225 | 32 |

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1. Bonser et al. J Am Coll Cardiol 2011;58:2455–74. 2. Pepper J et al. Ann Cardiothorac Surg 2016;5(4):360-367. 3. Chin et al. J Am Coll Cardiol. 2018 June 19; 71(24): 2773–2785. 4. Nardi et al. Vessel Plus 2017;1:77-83. 5. Merkle et al. Ther Adv Cardiovasc Dis 2018, Vol. 12(12) 327–340. 6. Rylski et al. Eur J Cardiothorac Surg 2017;51:1127–34. 7. Czerny et al. J Vis Surg 2018;4:14. 8. Shrestha et al.. Eur J Cardiothorac Surg 2017;51:i34–i39. 9. Tamura et al Eur J Cardiothorac Surg 2017;52:867–73. 10. Bing et al Vascular and Endovascular Surgery 2014, Vol. 48(3) 239-245. 11. Fattouch et al Ann Thorac Surg 2009;88:1244–50. 12. Evangelista et al. Circulation. 2012;125:3133-3141. 13. Geirsson A, et al. Eur J Cardio-Thorac Surg, 2007;32(2):255-262. 14. Czerny M, et al. JACC 2015;65(24):2628-2635. 15. Instructions for Use (IFU), Ascyrus Medical Dissection Stent. 16. Journal Pre-proof of Bozso SJ et al. "Midterm Outcomes of the Dissected Aorta Repair Through Stent Implantation Trial", The Annals of Thoracic Surgery (2020), doi: https://doi.org/10.1016/ j.athoracsur.2020.05.090. 17. Lee TC et al. J Card Surg. 2018;33:7–18. 18. Easo J et al. J Thorac Cardiovasc Surg 2012;144:617-23. 19. Grimm JC et al. Ann Cardiothorac Surg 2016;5(3):202-208. 20. Dumfarth J et al. Eur J Cardiothorac Surg 2018;53:1013–2.



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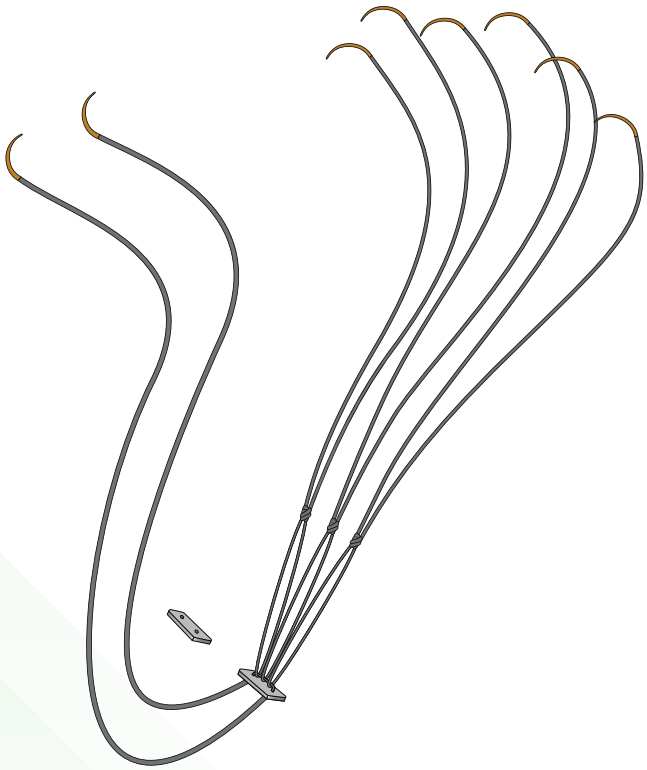
JT-BR-0980200-EN V03 06/2022

# Mitral Valve Solutions



## On-X®
## Mitral Heart Valves

## Chord-X®
## Mitral Chordal Replacement Products

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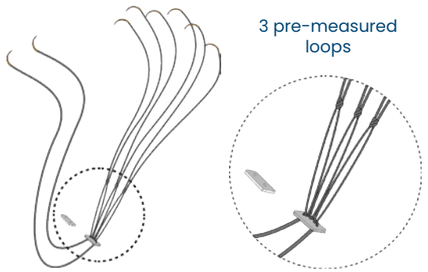
# Mitral Valve Solutions for Both Replacement and Repair

## Chord-X® Pre-Measured Loops:
### For Mitral Valve Repair

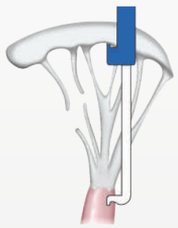



Chord-X is an innovative tool for mitral valve repair, and is designed to:

- Save time*,[1]
- Allow reproducible results
- Simplify mitral valve repair procedures

*Compared to artificial chords made by surgeon.

### Procedural Overview



Measure to Determine Size of Chord-X Artificial Chords

Papillary Muscle Attachment

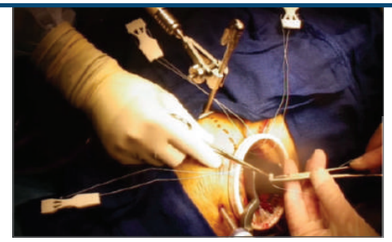
Leaflet Attachment

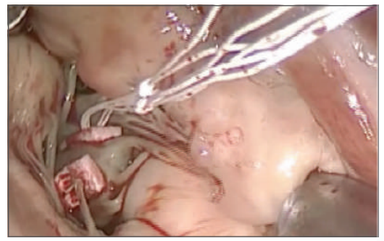
Implant Complete

See Instructions for Use for full details.[2]

## Mitral Valve Repair

**Chord-X Pre-Measured Loops provide an innovative solution to standardize, simplify, and save time for mitral valve repair**





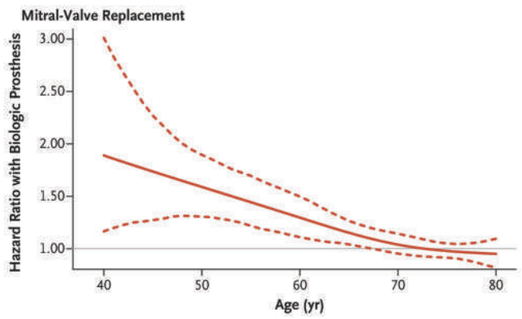
- Mitral valve repair is strongly preferred over replacement for primary MR whenever anatomically feasible.[3]
- Short- and long-term outcomes of successful valve repair for primary MR exceed those for valve replacement across all age ranges.[4]
- Chordal replacement may be associated with greater freedom from reoperation and may lead to improved postoperative left ventricular function compared with leaflet resection.[5]
- Chordal implantation keeps the door open for further treatments in case of MR recurrence.[6]

## If Mitral Valve Repair is not Possible, Consider Your Options for Mitral Valve Replacement

## Mitral Valve Replacement

### Mechanical Valves:

- "...mechanical valve prostheses remain the gold standard for valve replacement in younger individuals" when mitral valve repair is not possible[7]
- Mechanical mitral valve offers survival benefit at 15 years for patients <70[8] (see graph below)




### Tissue Valves:

- Calcification of leaflets increase valve gradients until reoperation is required[9,10]
- No guarantee patient will not need long term anticoagulation[9]
- More likely to require reoperation when compared to mechanical valves[8]
  - Note: 30-day mortality for all reoperative mitral valve replacement is 14%[8]

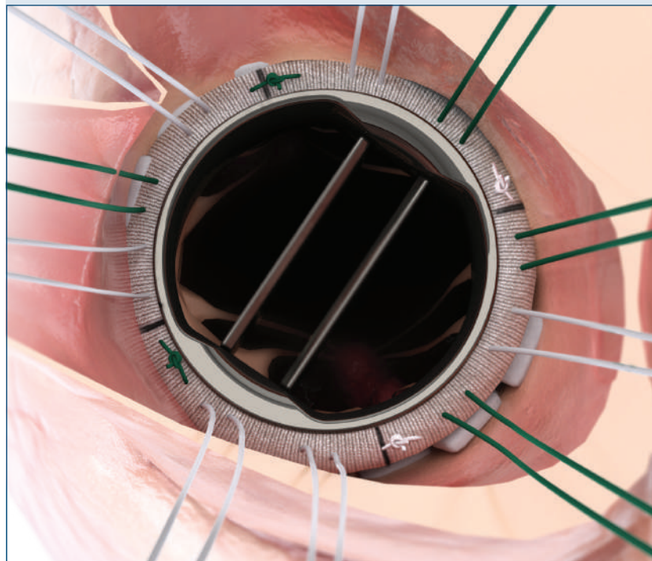
**The On-X Mitral Valve offers a "gold standard" solution for mitral valve replacement.[7]**

## On-X® Mitral Heart Valves:
### For Mitral Valve Replacement

90° Leaflet Opening

- Pure pyrolytic carbon for reduced thrombogenicity[11]
- ≤4.4 mm Hg across all valve sizes 25 – 33 mm[12]
- Sewing cuff designs made from polytetrafluoroethylene (PTFE)[12]
- Leaflet guards designed to prevent encroachment of subvalvular apparatus
- 90° leaflets and flared inlet designed to promote better laminar flow

### 90° Leaflet Opening



# Ordering Information

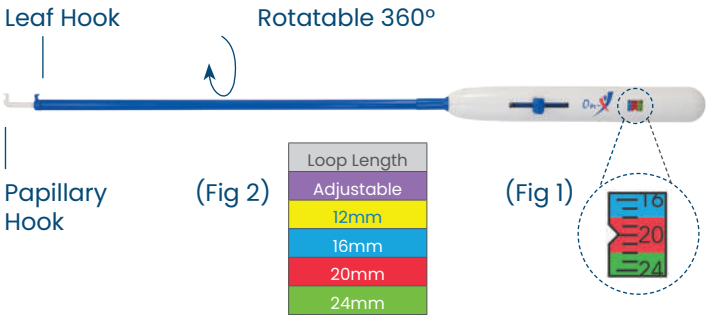
## Chord-X Pre-Measured Loops and Adjustable Suture System

| 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 |
|---|---|
| 23mm* | ONXM-23 |
| 25mm | ONXM-25 |
| 27/29mm | ONXM-27/29 |
| 31/33mm | ONXM-31/33 |

*Size 23 mitral valves are not available for sale in the United States.

## On-X Mitral Valve Conform-X Sewing Cuff

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

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Potential Adverse Events:
On-X: Adverse events potentially associated with the use of prosthetic heart valves (in alphabetical order) include, but are not limited to: angina, cardiac arrhythmia, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, myocardial infarction, prosthesis leaflet entrapment (impingement), prosthesis non-structural dysfunction, prosthesis pannus, prosthesis paravalvular leak, prosthesis regurgitation, prosthesis structural dysfunction, prosthesis thrombosis, stroke, and thromboembolism. It is possible that these complications could lead to: reoperation, explantation, permanent disability, or death.
Chord-X: Adverse events potentially associated with the use of any suture include: wound dehiscence, infection, and localized transitory inflammatory tissue reaction.


Reference:
1. Gillinov, et al., Ann Thor Surg 2016:102(3)e269–e271. 2. Chord-X Pre-Measured Loops and Chord-X Adjustable Suture System Instructions for Use. 3. 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;63:2459-2460. 4. O'Gara PT, Grayburn PA, Badhwar V, Afonso LC, Carroll JD, Elmariah S, Kithcart AP, Nishimura RA, Ryan TJ, Schwartz A, Stevenson LW. 2017 ACC expert consensus decision pathway on the management of mitral regurgitation. J Am Coll Cardiol 2017 Nov 7;70 (19):2421-2449. 5. 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. 6. Milind Y. et al., Outcomes in Degenerative Mitral Regurgitation: Current State-of-the Art and Future Directions. Progress In Cardiovascular Diseases 60 (2017) 370-385. 7. Chiu P, Goldstone AB, Woo YJ. Eur J Cardiothorac Surg 2018;54:622–6. 8. Goldstone AB et al. N Engl J Med 2017;377:1847-1857. 9. Nishimura et al., Circulation. 2017;135:e1159–e1195. 10. Rodrigues-Gabella, T. et al. J AM Coll Cardiol. 2018;71(13):1401-12. 11. 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. 12. On-X Prosthetic Heart Valve Instructions for Use.





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MLENG1331.001 (2022-08)

**The only Surgical Sealant Approved to Seal, Adhere and Reinforce Tissue[6]**

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*Data on file.

References:
1. Murdock MH, et al. Cytocompatibility and mechanical properties of surgical sealants for cardiovascular applications. The Journal of Thoracic and Cardiovascular Surgery. January 2019. 2. Feier H, et al. The Influence of Albumin/glutaraldehyde Sealant in Early Results After Acute Type A Aortic Dissection. REV.CHIM.(Bucharest) - 70 - No. 6 - 2019. 3. Chao HH. Torchiana DF. BioGlue: Albumin/ Glutaraldehyde Sealant in Cardiac Surgery. J Card Surg. 2003;18:500-3. 4. Fehrenbacher, JW. et al. Use of BioGlue in Aortic Surgery: Proper Application Techniques and Results in 92 Patients. The Hearth Surgery Forum #2006-1066 (5), 2005. 5. Internal BioGlue Bibliography. 6. BioGlue Summary of Safety and Effectiveness. 7. Bavaria JE, et al. Advances in the Treatment of Acute Type A Dissection: An Integrated Approach. Ann Thorac Surg 2002 74:S1848-52. 8. Weiner J, et al. Role of Bovine Serum Albumin-Glutaraldehyde Glue in the Formation of Anastomatic Pseudoaneurysms. J Card Surg 2011;26:76-81.



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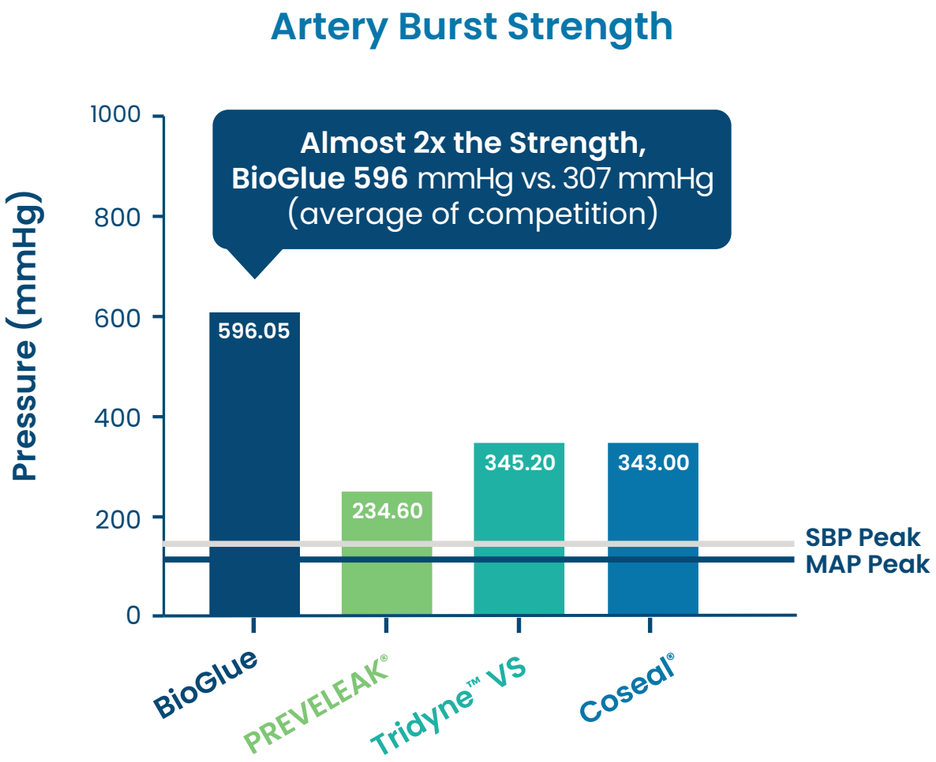
# Reinforcing Tissue, Reinforcing Results


ARTIVION™ | **BioGlue®** Surgical Adhesive

# BioGlue is the Strongest Surgical Sealant on the Market[1]

## Artery Burst Tests Show **BioGlue®** is **Significantly Stronger** Than PREVELEAK®, Coseal®, and Tridyne™ VS[1]




## **Reinforcing** Why BioGlue...

### Saves time in the OR[2,3]

- Reduces operating room time
- Reduces cross clamp time
- Reduces circulatory arrest time
- Reduces bypass time

### Saves your hospital money on blood products and hospital stays[3,4]

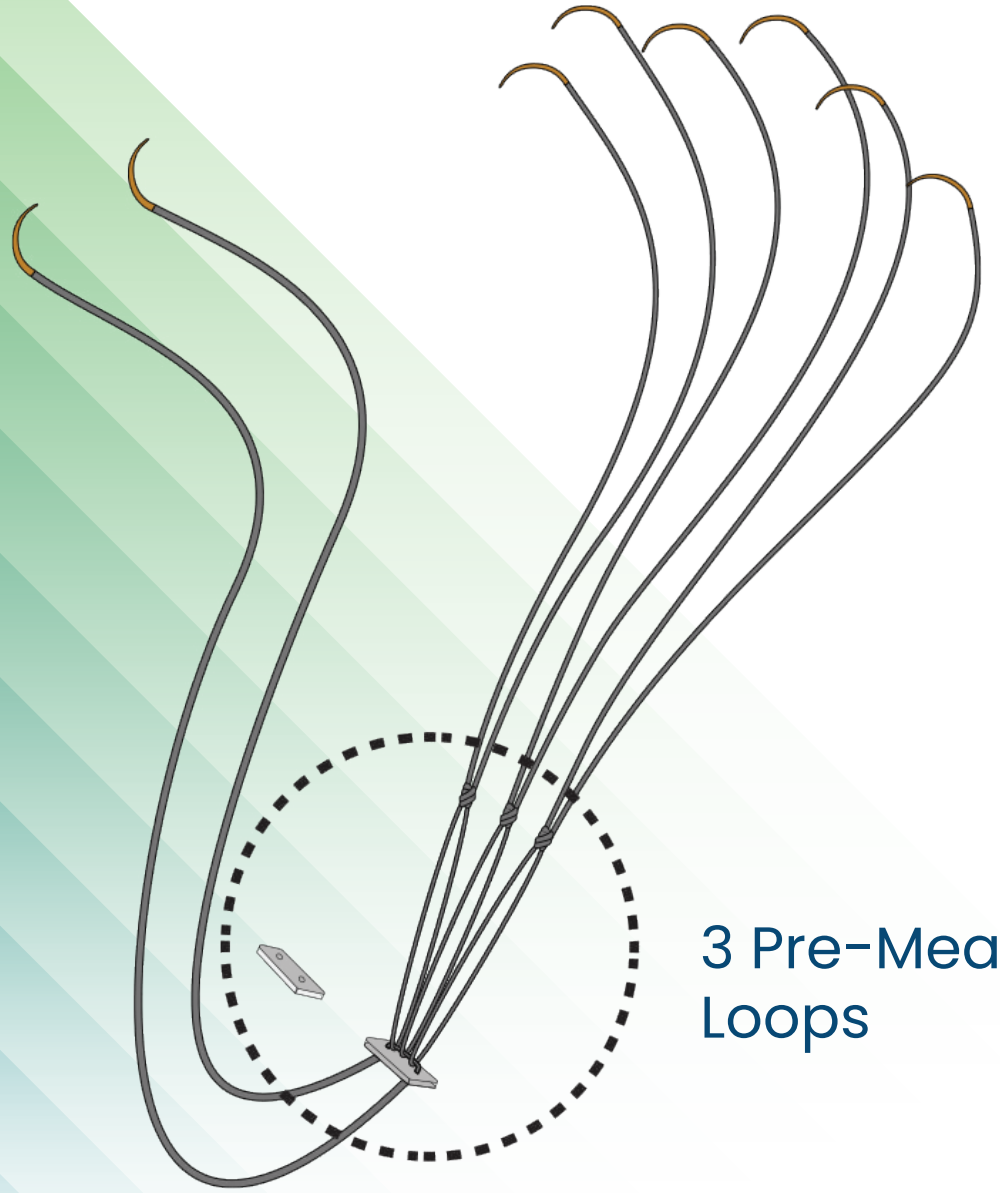
- Reduces platelets
- Reduces plasma
- Reduces blood cells

### Provides better clinical results[4,5,7,8]

- Lower mortality rates compared to standard surgical technique (8.6% vs. 15% respectively)
- Lower pseudoaneurysm rates comparing BioGlue to standard technique (2% vs. 3.8% respectively)
- Over 500 published preclinical and clinical papers

Since launch, **BioGlue** has been used in over **2.5 million procedures worldwide.***

# Standardize, Simplify and Save Time



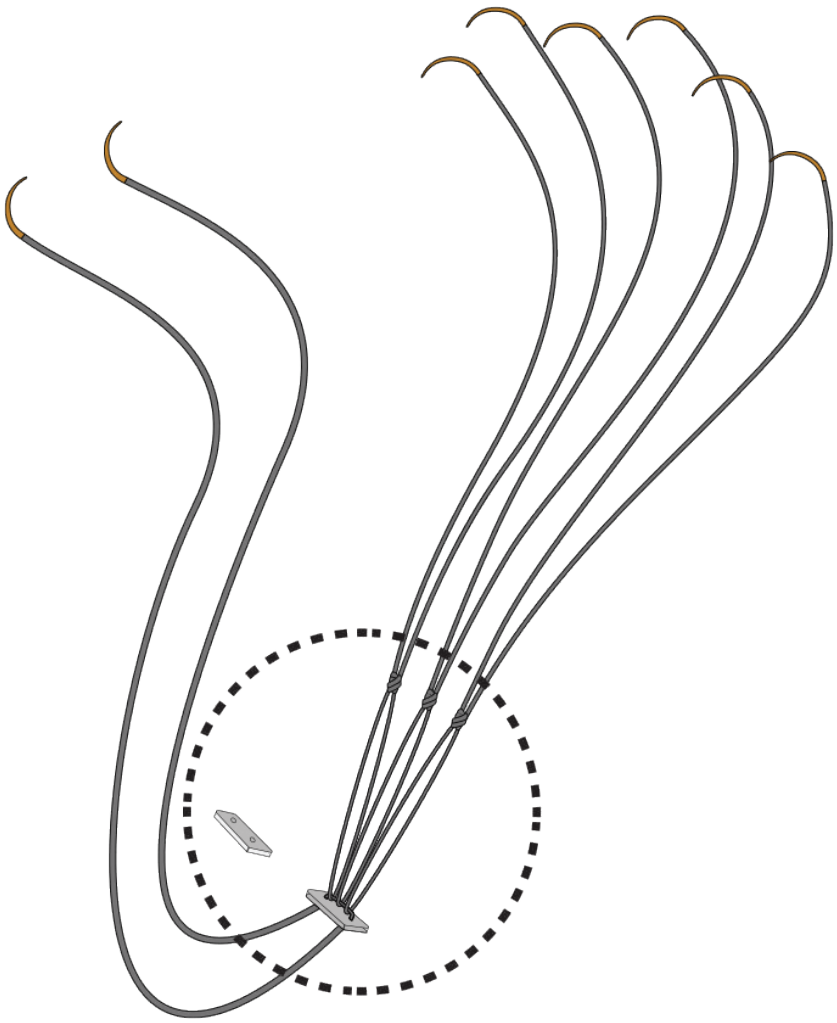
3 Pre-Measured Loops

ARTIVION | Chord-X®
Mitral Chordal Replacement Products

**Chord-X Pre-Measured Loops** and the **Chord-X Adjustable Suture System** are artificial chordae prostheses configured from non-absorbable, monofilament ePTFE suture with pledgets ready for mitral chordal implant.

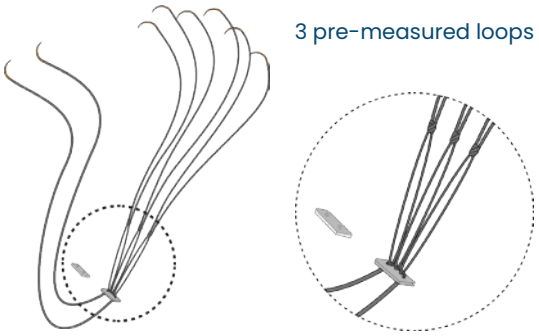
**The Chord-X Chordal Sizer** measures and indicates the required Chord-X prosthesis size needed. The Chord-X Chordal Sizer corresponds with a Chord-X Pre-Measured Loops and Adjustable Suture System using a color-coded sizing system. The Sizer also provides two hooks for loop creation and knot-tying.

Compared to artificial chords made by the surgeon during the procedure, Chord-X Mitral Chordal Replacement Products are designed to save time, allow reproducible results, and simplify procedures.



# Product Overview

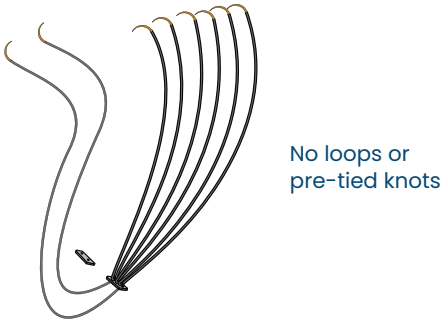
## Chord-X® Pre-Measured Loops




### Designed for the surgeon who prefers pre-measured chordal loops

- 3 x independent Chord-X Pre-Measured Loop lengths available in 12, 16, 20, and 24mm
- 2-0 USP ePTFE suture (diameter similar to GORE-TEX® CV-4)
- 1 x double armed papillary suture with a 3x7x1.85mm PTFE pledget
- 1 x independent 3x7x1.85mm PTFE pledget
- 18mm tapered point needles

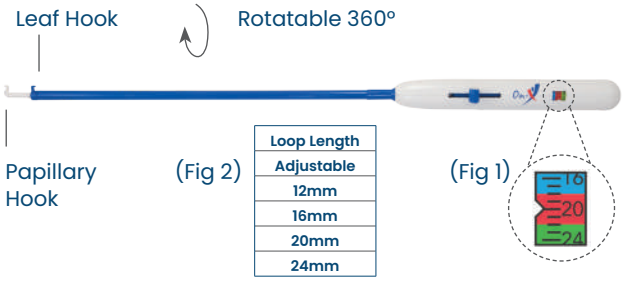
## Chord-X® Adjustable Suture System




### Designed for the surgeon to customize the length of chords

- 3 x independent double armed sutures (no loops or pre-tied knots)
- 2-0 USP ePTFE suture (diameter similar to GORE-TEX CV-4)
- 1 x double armed papillary suture with a 3x7x1.85mm PTFE pledget
- 1 x independent 3x7x1.85mm PTFE pledget
- 18mm tapered point needles

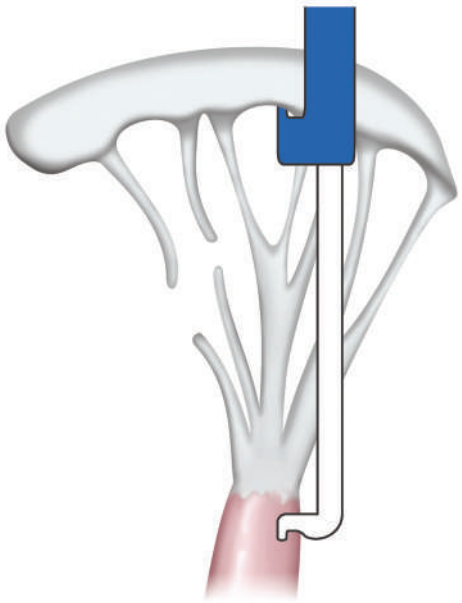
## Chord-X® Chordal Sizer



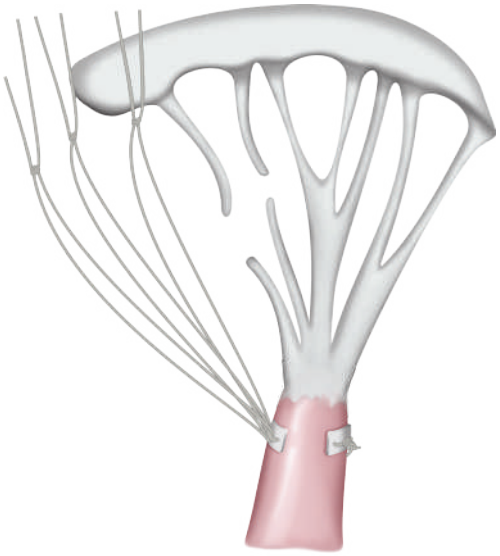

### Designed to measure and indicate the required Chord-X prosthesis size needed

- Color coded scale (Fig. 1) corresponds to Chord-X Pre-Measured Loops and Adjustable Suture System (Fig. 2)
- Provides fast and accurate sizing
- Rotatable sizing instrument for enhanced visualization

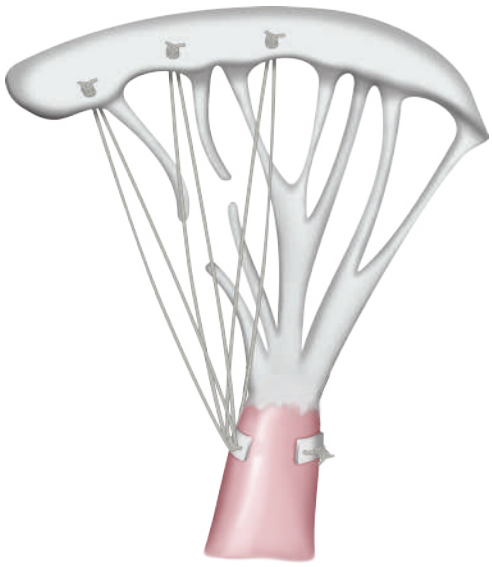
# Procedural Overview



Measure to Determine Size
of Chord-X Artificial Chords



Papillary Muscle Attachment

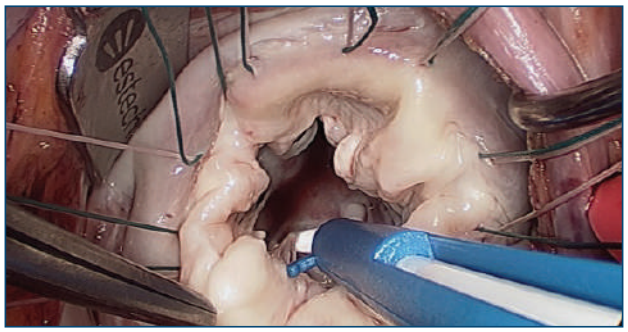


Leaflet Attachment

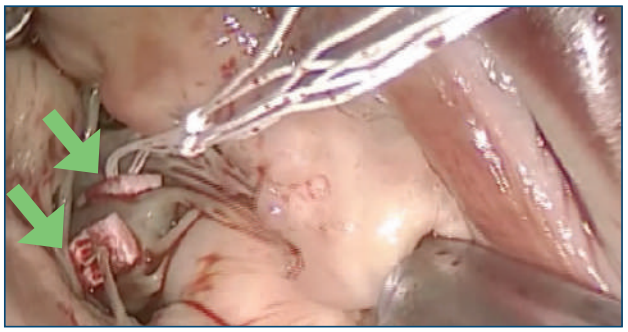
Implant Complete

See Instructions for Use for full details.[2]

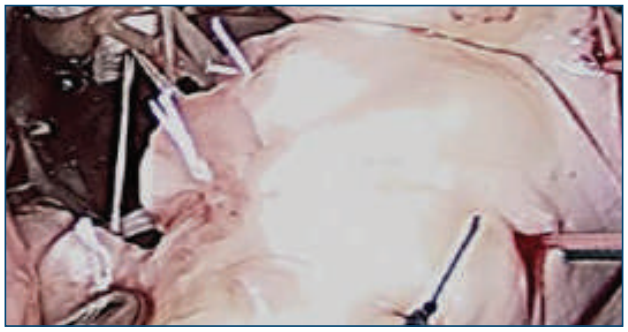
## Procedural Images



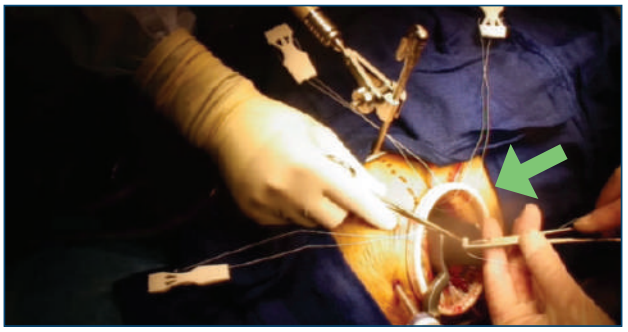
1. Chord-X Chordal Sizer used to determine chord length from papillary to leaflet



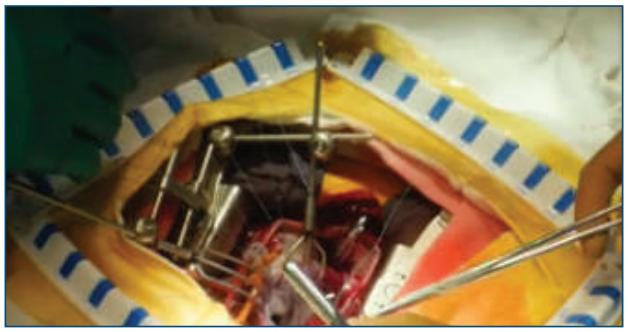
2. Chord-X Pre-Measured Loops have been attached to papillary (based on Chord-X Chordal Sizer measurement)



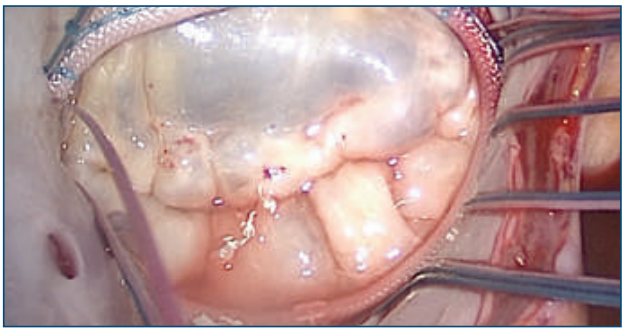
3. Chord-X Pre-Measured Loops attachments to leaflet with hand-tied knots are complete



4. The second pledget for Chord-X Pre-Measured Loops is being advanced over suture for papillary attachment



5. Chord-X Pre-Measured Loops may be placed in Gabbay-Frater Suture Guide™ (not required) for suture management



6. Coaptation confirmed with saline test

See Instructions for Use for full details.[2]

# Correcting Mitral Prolapse and Reducing Operative Time

"Intraoperative creation of chordal loops is tedious and adds to operative time. […] Chord-X Pre-Measured Loops […] can be used to correct prolapse at any site of the mitral valve. The Chord-X Loops facilitate mitral valve repair while reducing operative time."[1]

## 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 |

ARTIVION™

Learn more at **artivion.com**

References:
1. Gillinov, et al., Ann Thor Surg 2016:102(3)e269–e271. 2. Chord-X Pre-Measured Loops and Chord-X Adjustable Suture System Instructions for Use.



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