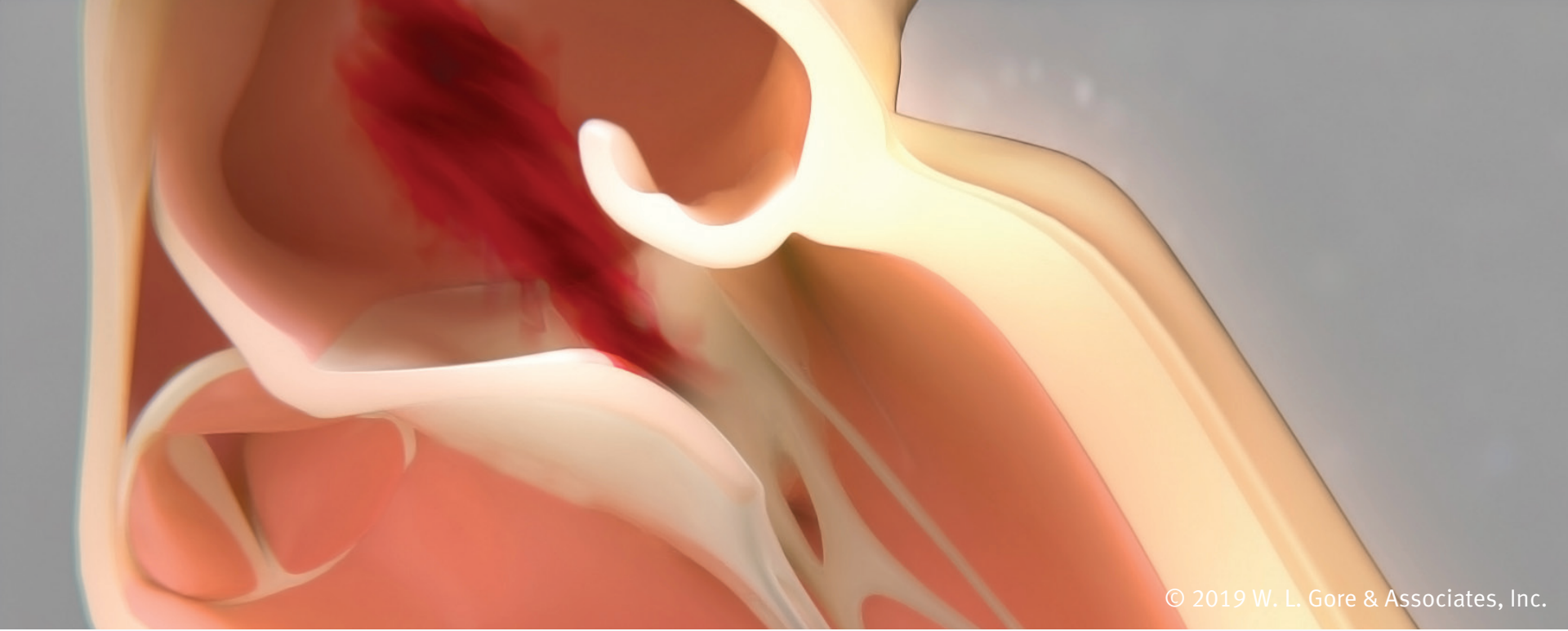

GORE-TEX® Suture for Chordae Tendineae Repair or Replacement

Products listed may not be available in all markets.

 AY1095-EN1 AUGUST 2019

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GORE-TEX® Suture cardiovascular offerings and *Indications for Use*

GORE-TEX® Suture for Chordae Tendineae Repair or Replacement

INDICATIONS: GORE-TEX® Suture for Chordae Tendineae Repair or Replacement is indicated for the repair or replacement of chordae tendineae.

CONTRAINDICATIONS: This device is contraindicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

GORE-TEX® Suture

INDICATIONS: GORE-TEX® Suture is indicated for use in all types of soft tissue approximation, including use in cardiovascular surgery. It is recommended for use where reduced suture line bleeding during cardiovascular anastomotic procedures is desired.

CONTRAINDICATIONS: This device is contraindicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

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Degenerative mitral regurgitation (MR) disease overview

- Disease progression / patient symptoms begin with labored breathing and can progress to heart failure
- Mitral valve leaflets fail to coapt allowing blood to leak into left atrium
- Most prevalent valve disease[1, 2]:
  - 0.6–1.7% of adult population, more than 10% in elderly
  - Estimated to affect 2.3 million U.S. adults by 2030
- Significantly underdiagnosed and undertreated; less than 1/6 diagnosed patients receive treatment[1, 2]
- Mitral valve surgery is the only Class I indicated treatment for[3]:
  - Symptomatic patients with chronic severe primary MR and LVEF > 30% (stage D)
  - Asymptomatic patients with chronic severe primary MR and LVEF 30% – 60% and / or LVESD ≥ 40 mm (stage C2)
- Mitral valve (MV) repair is preferred over MV replacement when possible[3]

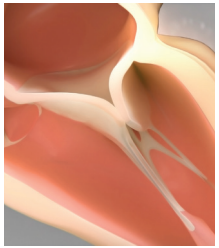

Figure 1. Normal valve

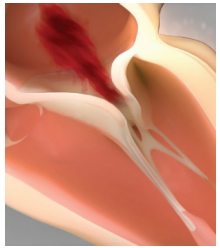

Figure 2. Degenerative MR (DMR) prolapse

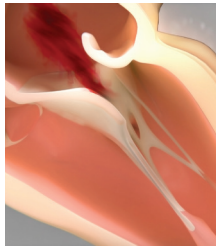

Figure 3. Degenerative MR flail

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2. Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M. Burden of valvular heart diseases: a population-based study. *Lancet* 2006;368(9540):1005-1011.
3. Nishimura RA, Otto CM, Bonow RO, Carabello BA, Erwin JP, 3rd, Fleisher LA, *et al.* 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology.* 2017;70(2):252-89.

Evolution and current approaches of DMR surgical repair

- 1969: Carpentier publishes the annuloplasty technique[1]
- 1978: Carpentier publishes the “French Correction” (annuloplasty, chordal transfer, and resection)[2,3]
- 1989: David publishes the first clinical uses of GORE-TEX® Suture for artificial chordal repair[4]
- Preference for chordal repair rather than resection has grown[5], supported by recent meta-analyses suggesting a lower reoperation rate[6,7]

Most common degenerative leaflet prolapse (DLP) repair techniques per 2018 STS database[8]

Technique	% of repairs
Annuloplasty (ring or band)	96.1%
Leaflet resection (all)	58.9%
Artificial ePTFE chords*	29.2%

* Median of 2 chords used (2–4 interquartile range)

1. Carpentier A. Reconstructive valvuloplasty. A new technique for mitral valvuloplasty. *Presse Medicale* 1969;77(7):1251-1253.
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3. Carpentier A. Cardiac valve surgery--the “French correction”. *Journal of Thoracic & Cardiovascular Surgery* 1983;86:323-337.
4. David TE. Replacement of chordae tendineae with expanded polytetrafluoroethylene sutures. *Journal of Cardiac Surgery* 1989;4(4):286-290.
5. Jouan J. Mitral valve repair over five decades. *Annals of Cardiothoracic Surgery* 2015;4(4):322-334.
6. Mazine A, Friedrich JO, Nedadur R, *et al.* Systematic review and meta-analysis of chordal replacement versus leaflet resection for posterior mitral leaflet prolapse. *Journal of Thoracic & Cardiovascular Surgery* 2018;155(1):120-128.e10.
7. Mihos C. A systematic review and meta-analysis of chordal replacement versus leaflet resection for isolated posterior mitral valve prolapse. *Journal of Cardiovascular Surgery* 2017;58(5):779-786
8. Gammie JS, *et al.* Isolated Mitral Valve Surgery: The Society of Thoracic Surgeons Adult Cardiac Surgery Database Analysis. *Annals of Thoracic Surgery* 2018;106(3):716-727.

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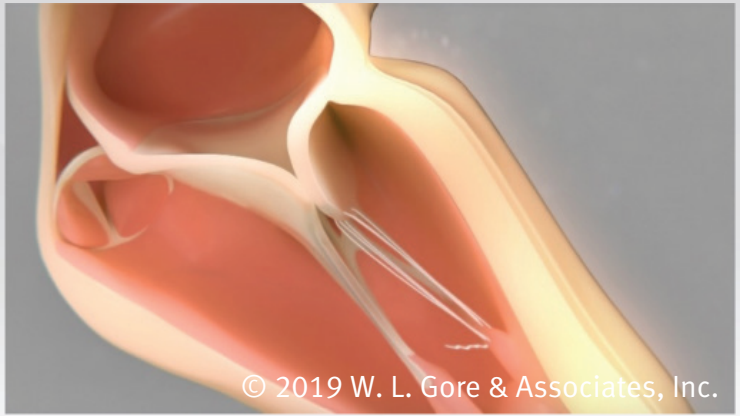
Chordal repair techniques

- Many techniques exist and continue to evolve[1,2], but most aim to mimic native architecture:
  - Leaflet attachment several mm from free edge, in rough zone / zone of coaptation
  - Ventricular attachment at the fibrous head of the papillary muscle
- Annuloplasty is almost always used, and occasionally ePTFE pledgets



1. Ibrahim M, Rao C, Athanasiou T. Artificial chordae for degenerative mitral valve disease: critical analysis of current techniques. *Interactive Cardiovascular & Thoracic Surgery* 2012;15(6):1019-1032.
2. Bizzarri F, Tudisco A, Ricci M, Rose D, Frati G. Different ways to repair the mitral valve with artificial chordae: a systematic review. *Journal of Cardiothoracic Surgery* 2010;5:22.

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Mitral valve architecture and function: Design considerations for artificial chordae

- Different chordae with different composition, properties and function[1–3]
- Primary (marginal or first-order) chords responsible for aligning leaflet free edge / coaptation zone under early systole (responsible for prolapse / MR)[1–3]

Conceptually ideal characteristics:

- High tensile strength and inelastic
- Resist thrombus and mineral deposition
- Resist creep, rupture over millions of cycles

YET

- Thin and supple
- Porous enough to enable tissue ingrowth
- Flexible over millions of cardiac cycles

1. Casado JA, Diego S, Ferreño D, *et al.* Determination of the mechanical properties of normal and calcified human mitral chordae tendineae. *Journal of the Mechanical Behavior of Biomedical Materials* 2012;13:1-13.
2. Obadia JF, Casali C, Chassignolle JF, Janier M. Mitral subvalvular apparatus: different functions of primary and secondary chordae. *Circulation* 1997;96(9):3124-3128.
3. Kunzelman KS, Cochran RP. Mechanical properties of basal and marginal mitral valve chordae tendineae. *ASAIO Transactions* 1990;36(3):M405-M408.

GORE-TEX® Suture clinical experience

- GORE-TEX® Suture obtained Pre-Market Approval (FDA) in 1985
- Multiple publications report 20–25 years of follow-up with GORE-TEX® Suture for chordal repair [1–3]
- Latest follow-up by David *et al.* reports three decades of experience[4]:
  - From 1985–2010, 858 consecutive patients treated with GORE-TEX® Suture
  - Mean follow-up of 13 years (IQR 8–17 years), 92 patients at risk at 20 years
  - Bileaflet / anterior / posterior prolapse 58, 13 and 28% respectively

Event-free survival and cumulative proportion of outcomes using competing risk models[4]

	5 years % [95%CI]	10 years % [95%CI]	15 years % [95%CI]	20 years % [95%CI]
Event free survival	93.4 [91.5 – 94.9]	84.9 [82.1 – 87.3]	73.4 [69.5 – 76.7]	61.5 [56.0 – 66.3]
Cardiac / valve death	2.3 [1.3 – 3.4]	4.4 [3.0 – 5.9]	8.1 [5.9 – 10.2]	12.4 [9.0 – 15.6]
Mitral valve reoperation	1.6 [0.8 – 2.5]	3.4 [2.1 – 4.6]	3.8 [2.4 – 5.2]	4.7 [3.0 – 6.4]
Moderate / severe MR	4.8 [3.8 – 6.0]	7.2 [5.9 – 8.8]	10.7 [8.6 – 13.2]	15.6 [12.0 – 20.0]

1. Hata H, Fujita T, Shimahara Y, Sato S, Ishibashi-Ueda H, Kobayashi J. A 25-year study of chordal replacement with expanded polytetrafluoroethylene in mitral valve repair. *Interactive Cardiovascular & Thoracic Surgery* 2015;20(4):463-468.
2. Salvador L, Mirone S, Bianchini R, *et al.* A 20-year experience with mitral valve repair with artificial chordae in 608 patients. *Journal of Thoracic & Cardiovascular Surgery* 2008;135(6):1280-1287.
3. David TE, Armstrong S, Ivanov J. Chordal replacement with polytetrafluoroethylene sutures for mitral valve repair: a 25-year experience. *Journal of Thoracic & Cardiovascular Surgery* 2013;145(6):1563-1569.
4. David TE, David C, Lafreniere-Roula M, Manlhiot C. Three decades of chordal replacement with GoreTex Sutures to correct mitral valve prolapse. Presented at the AATS 99th Annual Meeting. Presented at the American Association for Thoracic Surgery (AATS) 99th Annual Meeting; May 4-7, 2019; Toronto, Ontario, Canada. Abstract 203.

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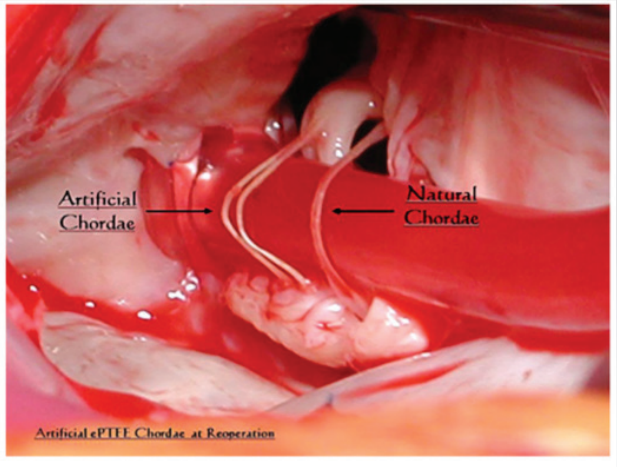
Chronic biological response and integration

- Generally observed that a fibrous / endothelial sheath eventually covers the suture, yielding a strong yet flexible thromboresistant suture indistinguishable from native chords after many years[1–4]



Artificial (GORE-TEX® Suture) and native chordae at 12 years post-implant[4]

1. Bortolotti U, Milano AD, Frater RW. Mitral valve repair with artificial chordae: a review of its history, technical details, long-term results, and pathology. *Annals of Thoracic Surgery* 2012;93(2):684-691.
2. Ibrahim M, Rao C, Savvopoulou M, Casula R, Athanasiou T. Outcomes of mitral valve repair using artificial chordae. *European Journal of Cardio-Thoracic Surgery* 2014;45(4):593-601.
3. Hata H, Fujita T, Shimahara Y, Sato S, Ishibashi-Ueda H, Kobayashi J. A 25-year study of chordal replacement with expanded polytetrafluoroethylene in mitral valve repair. *Interactive Cardiovascular & Thoracic Surgery* 2015;20(4):463-468.
4. Salvador L, Mirone S, Bianchini R, *et al.* A 20-year experience with mitral valve repair with artificial chordae in 608 patients. *Journal of Thoracic & Cardiovascular Surgery* 2008;135(6):1280-1287.

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