

# INSTRUCTIONS FOR USE FOR:



## ePTFE Nonabsorbable Monofilament

FOR CHORDAE TENDINEAE  
REPAIR OR REPLACEMENT

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## INSTRUCTIONS FOR USE FOR

**GORE-TEX® SUTURE**

for Chordae Tendineae Repair or Replacement  
ePTFE Nonabsorbable Monofilament

**DESCRIPTION**

GORE-TEX® Suture for Chordae Tendineae Repair or Replacement is a nonabsorbable, monofilament suture manufactured from expanded polytetrafluoroethylene (ePTFE) that has been expanded to produce a porous microstructure which is approximately 50% air by volume. The suture is undyed and contains no additives.

GORE-TEX® Sutures differ from USP requirements. See the table below for diameter-strength relationship.

GORE-TEX® Suture Size	Mean Diam. GORE-TEX® Suture (mm)	GORE-TEX® Suture Knot-Pull Tensile Strength (kg)
CV-2	.518	3.50
CV-3	.422	2.64
CV-4	.307	1.67
CV-5	.246	1.00
CV-6	.168	0.65

USP(mm) Size	USP Diam.		USP Limits on Avg. Knot-Pull Tensile Strength (kg)
	Min.	Max.	
0	.35	.399	2.16
2-0	.30	.339	1.44
3-0	.20	.249	0.96
4-0	.15	.199	0.60
5-0	.10	.149	0.40
6-0	.070	.099	0.20

The GORE-TEX® Suture is not absorbed or subject to weakening by the action of tissue enzymes. It does not degrade in the presence of infection. The internodal spaces permit infiltration of fibroblasts and leukocytes. Tissue attaches to and collagen penetrates into the GORE-TEX® Suture.

**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.

**WARNINGS**

Clinical studies have found that thread sizes CV-4 and CV-5 are adequate for replacement of primary chordae tendineae, with CV-6 threads occasionally suited for secondary chordae tendineae replacement. Data is not available for sizes CV-2 and CV-3 regarding effects of possible increased tissue ingrowth and changes in material pliability. Sizes CV-2 and CV-3 may be useful for chordae tendineae replacement as an adjunct to prosthetic valve replacement.

The replacement of chordae tendineae requires accurate sizing to ensure satisfactory functioning of the valve mechanism. Chordae tendineae replaced with sutures that are either too long or too short can result in failure to correct valvular incompetence. See the Recommended Techniques Section for determining correct suture length.

Do not use in the presence of infectious endocarditis.

Tissue invasion of the GORE-TEX® Suture can result in attachment of the suture to the tissue it penetrates. Such attachment may make removal of the GORE-TEX® Suture difficult.

**PRECAUTIONS**

Successful use of this device requires appropriate training and experience in cardiac surgical techniques including mitral valve repair.

Do not alter the usual practice of pre, peri, or post operative administration of anticoagulation therapy.

Misuse of this suture, like any other suture, can result in severe injury or death to the patient. As with any suture, care should be taken to avoid damage when handling. Avoid crushing or crimping the suture with surgical instruments or exposing the suture to sharp edges.

At least seven, equally tensioned, flat square throws are required to produce a secure knot when tying GORE-TEX® Suture for Chordae Tendineae Repair or Replacement. Additional throws may be necessary depending on surgical circumstances. When tying knots with the GORE-TEX® Suture, tension should be applied by pulling each strand of the suture in opposite directions with equal force. As the knot is tensioned, the air in the suture is forced out. Care should be taken to avoid using a jerking motion which could break the suture. Uneven tensioning of a well formed square knot may result in an unsecure knot. When the GORE-TEX® Suture is properly tensioned and formed, standard surgical knotting techniques will produce a secure knot.

## RECOMMENDED TECHNIQUES

### Suture Placement:

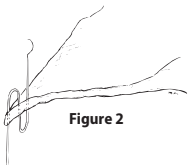
1. After determining the number of chordae tendineae that will be replaced, a GORE-TEX® Suture is placed through the papillary muscle, with a pledget placed on each side of the muscle (Figure 1). The suture is then tied. This knot should be tied loosely to avoid ischemia to the tip of the muscle.



**Figure 1**

2. After all of the sutures have been anchored to the papillary muscle, the two sides of each suture are run through the free margin of the leaflet (approximately 2 mm apart). It is useful to increase the friction of the suture in the leaflet to minimize suture slippage during the suture length adjustment steps. Therefore, pass each side of the suture through the leaflet twice (Figure 2).

An autogenous or thin ePTFE pledget may be placed on the atrial side of the leaflet for reinforcement (Figure 3).



**Figure 2**



**Figure 3**

### Establishing Chordae Tendineae Length:

1. The remaining valve repair procedures are completed, and the length of each chordae tendineae replacement suture is then established. Suture lengths are set to maintain the opposing points of the two leaflets at the same level in the ventricle.
2. Saline solution is injected into the ventricular cavity to close the valve (with aortic root venting for de-airing). If residual regurgitant jets are present or the closure line is not symmetrical, adjust the length of the GORE-TEX® Sutures.

3. Knot the GORE-TEX® Suture ends using at least seven flat square throws. Care should be taken to avoid altering the length of the suture while knotting. Shortening of the artificial chordae while knotting could result in over-correction of the leaflet prolapse and restrict the leaflet motion.
4. After the patient is off cardiopulmonary bypass, transesophageal echocardiography should be used to confirm the results of the hydrodynamic testing and evaluate the valve repair.

### References:

Zussa, Claudio. Different applications of ePTFE valve chordae: surgical technique. *J Heart Valve Disease*, 1996; 5:356-361.

Frater, RWM, Gabbay, S, Shore, D, et al. Reproducible replacement of elongated or ruptured mitral valve chordae. *Ann Thorac Surg* 1983;35:14-28.

Zussa, Claudio. *Artificial Chordae in Mitral Valve Surgery*. Austin: R.G. Landes Company, 1994: 159.

### ADVERSE REACTIONS

Potential adverse effects associated with the use of any suture include: wound dehiscence, infection, and localized transitory inflammatory tissue reaction.

### HOW SUPPLIED

GORE-TEX® Sutures for Chordae Tendineae Repair or Replacement are available as sterile strands in sizes CV-2 through CV-6, with or without ePTFE Pledgets.

GORE-TEX® Sutures for Chordae Tendineae Repair or Replacement are supplied **STERILE** unless the integrity of the package has been compromised. The device is for single use only. Do not resterilize.



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