

INSTRUCTIONS FOR USE FOR:



ePTFE Nonabsorbable Monofilament

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INSTRUCTIONS FOR USE FOR:

GORE-TEX® SUTURE ePTFE Nonabsorbable Monofilament

DESCRIPTION

The GORE-TEX® Suture is a nonabsorbable, monofilament suture manufactured from polytetrafluoroethylene (PTFE) that has been expanded to produce a porous microstructure which is approximately 50% air by volume. The porous nature of the GORE-TEX® Suture enables it to be swaged to needles that closely approximate the diameter of the thread, without compromising the strength of the needle attachment. Clinical and laboratory testing demonstrates that GORE-TEX® Sutures can reduce suture line bleeding. Bench testing with dura substitute materials indicates reduced needle hole fluid leakage when using the GORE-TEX® Suture in dura mater repairs. The suture is undyed and contains no additives.

GORE-TEX® Suture has been specifically designed for cardiovascular surgery. Clinical trials have demonstrated it is also suitable for general surgery.

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-0	.626	5.27
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
CV-7	.109	0.40
CV-8	.091	0.30

USP Size	USP Diam. (mm)		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
7-0	.050	.069	0.11
8-0	.040	.049	0.06

ACTIONS

PTFE is one of the most inert materials known and has been shown in clinical trials to elicit minimal tissue reaction. 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. This incorporating response may actually reinforce the action of the suture, strengthening the surgical closure with time.

INDICATIONS

The GORE-TEX® Suture is indicated for use in all types of soft tissue approximation, including use in cardiovascular surgery and dura mater repair. 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.

WARNINGS

The safety and effectiveness of this suture in peripheral neural, microsurgical and ophthalmic applications has not been established.

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.

This device is for single use only. Do not resterilize.

PRECAUTIONS

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. In order to minimize needle damage, do not drive the needle from the channel where the suture is attached.

As with all sutures, knot security requires standard surgical techniques of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon.

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.

STERILITY

The GORE-TEX® Suture is supplied **STERILE**. Provided that the package is not compromised in any way, the package will serve as an effective sterile barrier until the "Use By" (expiration) date printed on the box. This device is for single use only. Do not resterilize.

ADVERSE REACTIONS

None reported.

DOSAGE AND ADMINISTRATION

Use as required per surgical procedure.

HOW SUPPLIED

GORE-TEX® Sutures are available as sterile strands in a variety of sizes and lengths, with and without permanently attached needles.

DEFINITIONS



Use By



Attention, See Instructions for Use



Do Not Re-Use



Catalogue Number



Batch Code



European Authorized Representative



Contents sterile unless package has been opened or damaged.



Contents sterile unless enclosed package has been opened or damaged. Sterilized by ethylene oxide.



Quantity



Piercing Point Needle



Reverse Cutting Needle



Taper Point Needle



AM0136-ML1



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Worldwide*

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For international contact and additional
product information, visit

www.goremedical.com

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