General company information

Company name
W. L. Gore & Associates, Inc.

Address:
1505 N. Fourth Street
Flagstaff, AZ 86004 USA
Telephone: 800 528 8763
Fax: 800 942 5315

Email address:
mpdcustomercare@wlgore.com

Internet website:
www.goremedical.com/eu

Manufacturer
W. L. Gore & Associates, Inc.
Medical Products Division
1505 N. Fourth Street
Flagstaff, AZ 86004 USA

Quality System certification
The Quality System is certified to be in accordance with ISO 13485.

Certifier of the Quality System
The Quality System is audited annually by the European Notified Body BSI Group, The Netherlands B.V. CE 2797

Certifier website
www.bsigroup.com

Regulatory affairs
Email: TDS@wlgore.com

TECHNICAL DATA SHEET

Product information

Product Name
GORE-TEX® Suture

Synonym
Thread

Description and photo

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. The microporous structure facilitates tissue attachment using minimal surface friction and reduction of needle hole leakage. The suture is undyed and contains no additives.

GORE-TEX® Suture

Size	GORE-TEX® Suture limits on avg. knot-pull tensile strength (kg)
CV-8	0.075
CV-7	0.138
CV-6	0.25
CV-5	0.50
CV-4	0.75
CV-3	1.20
CV-2	1.8
CV-0	2.7

Indications for use/contraindications

Indications for use:

The GORE-TEX® Suture is indicated for use in surgical procedures where general soft tissue approximation and/or ligation is required including cardiovascular surgery, repair of mitral valves, and the replacement of chordae tendineae.

Contraindications:

No known contraindications.

Item references

The first number describes the caliber of the thread: CV-0, CV-2, CV-3, CV-4, CV-5, CV-6, CV-7, CV-8

The letter describes the length of the thread: J = 46 cm, K = 61 cm, M = 76 cm, N = 91 cm, U = 122 cm

Last two numbers indicate a single or double needle: Even = double needle, Odd = single needle

Europe

CE mark

Applicable CE directive: (EU) 2017/745 (MDR)

European medical device classification: Class III

CE certificate number: MDR 764344

Notified body: BSI Group, The Netherlands B.V. CE 2797

Original date of CE marking: 1995

Conformity assessment: Annex IX

Packaging characteristics

Product is packaged in a sterile barrier pouch and then placed into a multi-pack cardboard shelf carton.

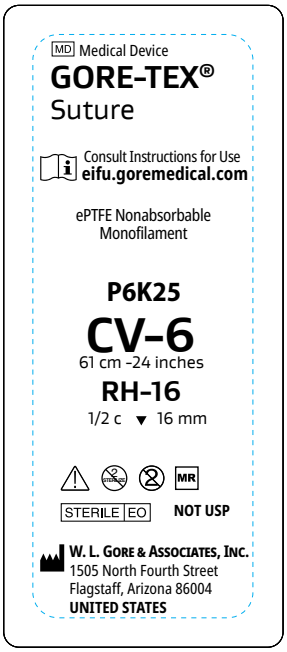
Size of the GORE-TEX® Suture carton

Thread count	Carton size (mm) Length x width x depth	Maximum weight (kg)
12	149 x 60 x 57	0.15

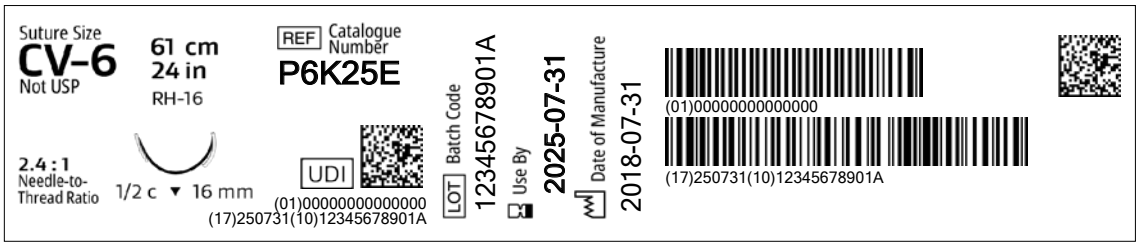
Delivery unit: 1 box of 12 threads

Minimum quantity for delivery: 1 box of 12 threads

Primary packaging



Secondary packaging



GORE-TEX®
Suture
Together, improving life
ePTFE Nonabsorbable Monofilament
en GORE-TEX® Suture
cs Šicí vlákno GORE-TEX®
da GORE-TEX® sutur
nl GORE-TEX®-Hechtdraad
fi GORE-TEX®-ommellanka
fr Fil de Suture GORE-TEX®
de GORE-TEX® Nahtmaterial
el Ράμμα GORE-TEX®
hu GORE-TEX® Varrat
it Filo da Sutura GORE-TEX®
no GORE-TEX® Sutur
pl Szew GORE-TEX®
pt Sutura GORE-TEX®
es Sutura GORE-TEX®
sv GORE-TEX® Sutur
tr GORE-TEX® Sütür
Consult Instructions for Use
eifu.goremedical.com
GORE-TEX®
Suture
CV-0
91 cm
36 in
THX 26
0N05E
1:3:1
(01)00000000000000
(17)250731(10)12345678901A
2018-07-31
2025-07-31
1234567890 1A
Consult Instructions for Use
eifu.goremedical.com
Caution
Do Not Reuse
Do Not Resterilize
Keep Dry
MR Safe
Store at 15°C-30°C
Do Not Use if Package is Damaged
Rx Only
Single Sterile Barrier with Protective Packaging Inside
STERILE EO Sterilized using Ethylene Oxide
12 QTY Quantity
30257665
Manufacturer
W. L. Gore & Associates, Inc.
1505 North Fourth Street
Flagstaff, Arizona 86004
UNITED STATES
goremedical.com
EC REP Authorised Representative in the European Community
W. L. Gore & Associates B.V.
Ringbaan Oost 152A
5013CE Tilburg
NETHERLANDS
Importer into the European Community
CE 2797
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Recyclable Packaging Material

Labeling definitions

EC REP	Authorised Representative in the European Community
LOT	Batch Code
REF	Catalogue Number
	Caution
	CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.
	Consult Instructions for Use
	Date of Manufacture
	Do Not Resterilize
	Do Not Reuse
	Do Not Use if Package is Damaged
	Importer into the European Community
	Keep Dry
	Manufacturer
MD	Medical Device
MR	MR Safe
	Single Sterile Barrier System with Protective Packaging Inside
STERILE EO	Sterilized using Ethylene Oxide
	Store at 15°C - 30°C
UDI	Unique Device Identifier
	Use By
	Piercing Point Needle
QTY	Quantity
▼	Reverse Cutting Needle
	Taper Point Needle

Barcode

The barcode follows the global standards 1 (GS1) system (www.gs1.org).

Sample barcode:

Contains the Device Identifiers (DI) or GTIN: (01)00733132610235

(01)	GS1 Application Identifier for GTIN
0	Indicator Digit (Packaging Level Indicator)
0733132	GS1 Company Prefix (GPC)
61023	Manufacturer Item Reference
5	and check digit

Contains the Production Identifiers (PI): (17)130831(10)06452037

(17)	GS1 Application Identifier for Expiry Date
130831	Expiry Date in YYMMDD GS1 Format
(10)	GS1 Application Identifier for Lot Number (NOTE: (21) for Serial Number)
06452037	Lot Number

Traceability

The traceability is secured by the unique device identification (UDI) included in the package labels and carton labels.

Product components

Main components:

- ePTFE (expanded polytetrafluoroethylene)
- 300-series stainless steel (with or without silicone coating)

The following chemicals and substances are not used in the manufacture of this product or packaging materials:

- Latex
- Phthalates
- Polyvinyl Chloride
- Animal Origin Substances

Sterilization

Sterilization procedure:

The sterilization by ethylene oxide is certified to be in accordance with the standard ISO 11135.

Mode of cleaning/resterilization:

The GORE-TEX® Suture is designed for single use only; do not reuse device. Do not resterilize.

Storing and stocking conditions

Storing conditions:

Keep dry and store at 15°C - 30°C.

Product shelf life:

Provided that the integrity of the package is not compromised in any way, the shelf-life of the device is five years. Do not use the device beyond the “Use By” expiration date printed on the box.

Additional information

MRI safety:

MR Safe – Needles are not intended to be implanted.

Risk management:

The Risk Management process utilizes established procedures to identify, analyze, control, and monitor risks as they apply to medical device product safety. These activities are reviewed and documented in accordance with ISO 14971.

Biocompatibility:

Biocompatibility per ISO 10993-1

Suggested reading:

Soft tissue approximation and/or ligation

Cahill J, Northeast AD, Jarret PE, Leach RD. Sutures for inguinal herniorrhaphy--a comparison of monofilaments with PTFE. *Ann R Coll Surg Engl*. 1989;71(2):128-130.

Chiesa R, Marone EM, Tshomba Y, Logaldo D, Castellano R, Melissano G. Aortobifemoral bypass grafting using expanded polytetrafluoroethylene stretch grafts in patients with occlusive atherosclerotic disease. *Ann Vasc Surg*. 2009;23(6):764-769.

Franco J, Kelly E, Kelly M. Periareolar augmentation mastopexy with interlocking gore-tex suture, retrospective review of 50 consecutive patients. *Arch Plast Surg*. 2014;41(6):728-733.

Garcia-Rinaldi R, Revuelta JM, Poeppel K, Treager K, Black D, Kirby JM. Clinical experience with expanded polytetrafluoroethylene suture. *Boletín de la Asociación Médica de Puerto Rico*. 1986;78(8):335-338.

Karapantzou C, Dressler D, Rohrbach S, Laskawi R. Frontalis suspension surgery to treat patients with essential blepharospasm and apraxia of eyelid opening-technique and results. *Head Face Med*. 2014;10:44.

Yaman D, Paksoy T, Ustaoglu G, Demirci M. Evaluation of Bacterial Colonization and Clinical Properties of Different Suture Materials in Dentoalveoler Surgery. *J Oral Maxillofac Surg*. 2022;80(2):313-326.

Chordae tendineae replacement

Chotivatanapong T, Chaiseri P, Kasemsarn C, Sungkahapong V. Chordal replacement with expanded polytetrafluoroethylene suture: Early results. *Asian Cardiovasc Thorac Ann*. 1998;6(1):49-51.

David TE, David CM, Lafreniere-Roula M, Manlhiot C. Long-term outcomes of chordal replacement with expanded polytetrafluoroethylene sutures to repair mitral leaflet prolapse. *J Thorac Cardiovasc Surg*. 2020;160(2):385-394.e381.

Domenech A, Marenchino RG, Posatini R, Fortunato GA, Rossi E, Kotowicz V. Leaflet resection versus chordal replacement for degenerative mitral regurgitation: Long-term outcomes according to the technique used. *Rev Argent Cardiol*. 2019;87(3):187-192.

Hysi I, Gautier L, Rebet O, Carjaliu I, Radutoiu M, Fabre O. Standardized loop technique for mitral valve repair offers good midterm results. *Asian Cardiovasc Thorac Ann*. 2020;28(8):482-487.

Kakuta T, Fukushima S, Shimahara Y, et al. Early results of robotically assisted mitral valve repair in a single institution: report of the first 100 cases. *Gen Thorac Cardiovasc Surg*. 2020;68(10):1079-1085.

Kasegawa H, Shimokawa T, Shibazaki I, Hayashi H, Koyanagi T, Ida T. Mitral Valve Repair for Anterior Leaflet Prolapse With Expanded Polytetrafluoroethylene Sutures. *Ann Thorac Surg*. 2006;81(5):1625-1631.

Lewis CT, Stephens RL, Tyndal CM, Cline JL. Concomitant robotic mitral and tricuspid valve repair: technique and early experience. *Ann Thoracic Surg*. 2014;97(3):782-787.

Maeda S, Funatsu T, Kondoh H, *et al*. Intermediate-term outcomes of our original multiple-knot technique using ePTFE sutures for anterior mitral leaflet prolapse. *Surg Today*. 2019;49(4):350-356.

Ma J, Liu J, Wei P, *et al*. Quadrangular resection versus chordal replacement for degenerative posterior mitral leaflet prolapse. *Ann Transl Med*. 2021;9(1):Med.

Mutsuga M, Tokuda Y, Fujimoto K, *et al.* Surgery for Anomalous Papillary Muscle Directly Into the Anterior Mitral Leaflet. *Ann Thoracic Surg*. 2021;111(5):1512-1518.

Takahashi Y, Abe Y, Fujii H, Morisaki A, Sakon Y, Shibata T. Loop technique for degenerative mitral regurgitation due to extended prolapse. *J Card Sur*g. 2021;36(12):4485-4496.

Woo YJ, MacArthur JW, Jr. Posterior ventricular anchoring neochordal repair of degenerative mitral regurgitation efficiently remodels and repositions posterior leaflet prolapse. *European journal of cardio-thoracic surgery: official journal of the Eur J Cardiothorac Surg.* 2013;44(3):485-489; discussion 489.

Consult Instructions for Use
eifu.goremedical.com

Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.

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