

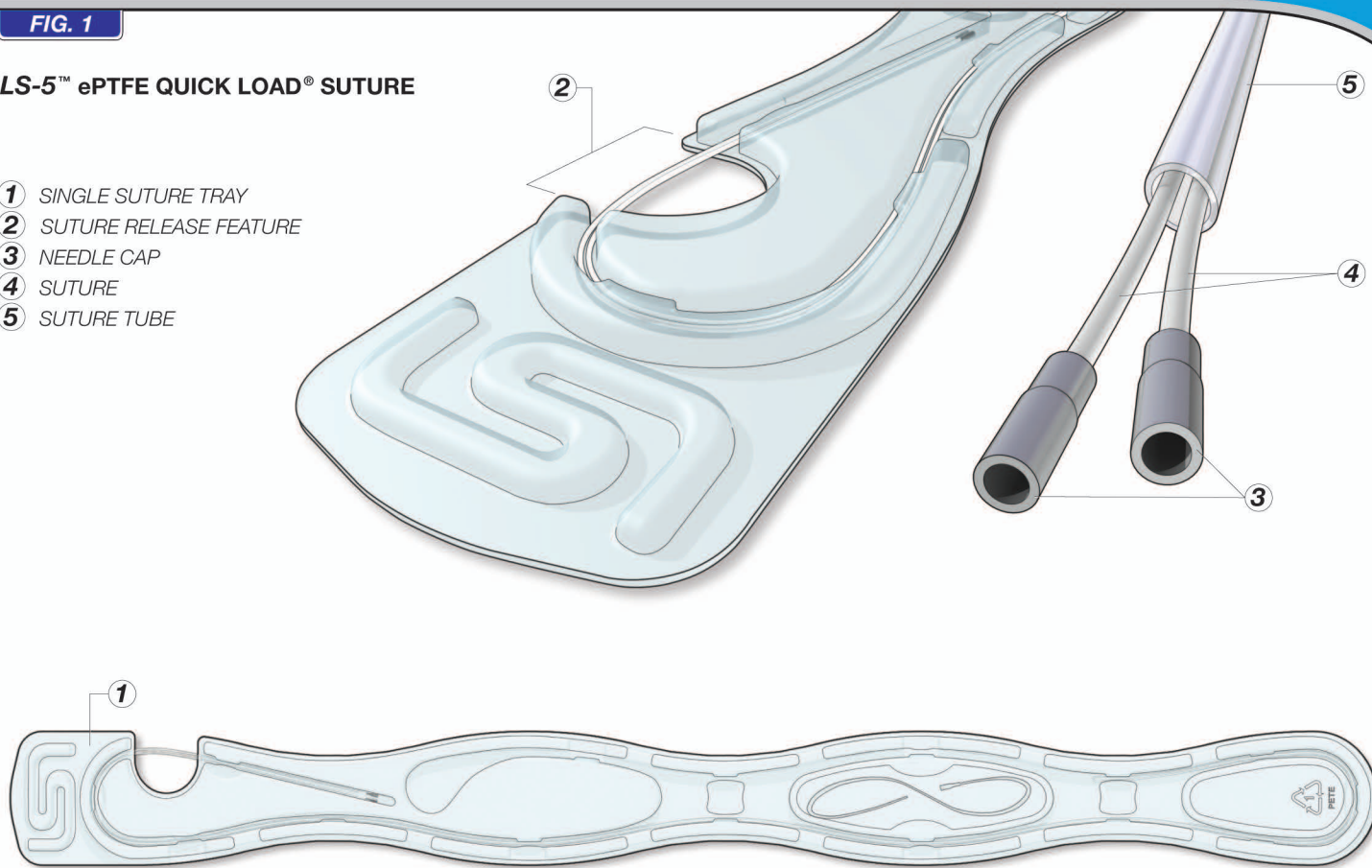
LS-5™ ePTFE QUICK LOAD® SUTURE TECHNOLOGY GUIDE

 READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1

LS-5™ ePTFE QUICK LOAD® SUTURE

- ① SINGLE SUTURE TRAY
- ② SUTURE RELEASE FEATURE
- ③ NEEDLE CAP
- ④ SUTURE
- ⑤ SUTURE TUBE



DESCRIPTION

Each LSI SOLUTIONS® LS-5™ ePTFE QUICK LOAD® sterile surgical suture with 2 needle caps is held in a customized tray (①), with a suture release feature (②) and is intended for single patient use. The LS-5™ ePTFE QUICK LOAD® suture is designed to enable the rapid, easy and reliable loading of suture into compatible LSI SOLUTIONS® suturing devices. LS-5™ ePTFE QUICK LOAD® suture is a non-absorbable monofilament expanded polytetrafluoroethylene (ePTFE) suture. A short length of modified surgical stainless steel tubing, called a "needle cap" (③), is attached to each end of the suture (④) for interfacing with LSI suturing devices. The LS-5™ ePTFE QUICK LOAD® suture also includes a detachable clear suture tube (⑤) to keep the suture from tangling. The LS-5™ ePTFE QUICK LOAD® surgical suture is undyed and contains no additives.

INDICATIONS

LS-5™ ePTFE QUICK LOAD® surgical suture is indicated for use in all types of soft tissue approximation, including use in cardiovascular surgery.

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STERILE EO

Rx Only



MD

MR

Symbol Glossary: www.lsisolutions.com/symbols



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with our LSI SOLUTIONS®
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ACTIONS

ePTFE suture is a very inert suture material known to elicit minimal tissue reaction. LS-5™ ePTFE suture is not absorbed and is not known to degrade or lose strength over time. No significant loss in tensile strength retention occurs in vivo. The LS-5™ ePTFE QUICK LOAD® surgical suture is MR safe.

CONTRAINDICATIONS

- The LS-5™ ePTFE QUICK LOAD® surgical suture is contraindicated for use in ophthalmic surgery, microsurgery, and neural tissue.
- Do not use this suture under conditions in which excessive suture tension can lead to tissue damage.

WARNINGS

- Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.
- Do not resterilize.** The performance of the LS-5™ ePTFE QUICK LOAD® surgical suture after cleaning or other reprocessing has not been verified and is not supported by LSI SOLUTIONS, Inc.
- Discard open (unsealed), unused, or damaged suture or suture in damaged primary packaging.
- As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.
- Minimally invasive surgical procedures should only be performed by physicians having adequate training and familiarity with minimally invasive techniques. In addition, medical literature should be consulted relative to techniques, complications and hazards prior to the performance of minimally invasive procedures.
- Users should be familiar with surgical procedures and techniques involving suture before employing the LS-5™ ePTFE QUICK LOAD® surgical suture for wound closure, as the risk of wound dehiscence may vary with the site of application.
- Acceptable surgical practice and good surgical judgement must be followed with respect to drainage and closure of infected or contaminated wounds.
- Redundant, cut-away suture remnants and used needle caps, along with packaging, must be inspected, handled and disposed of consistent with standard, accepted medical device disposal procedures.
- Applications other than for soft tissue approximation, can result in failure to pick up suture or in damage to the suturing device rendering either unsuitable for continued use.
- Never drive the suturing needle into suture, bone, dense ligamentous tissue, severely calcific tissue or other instruments.
- Do not leave any foreign material (e.g. suture fragment, needle caps, etc.) unattached in areas potentially exposed to circulating blood.
- The LS-5™ ePTFE QUICK LOAD® surgical suture is intended for single patient use only.
- Tissue invasion of the LS-5™ ePTFE QUICK LOAD® surgical suture can result in attachment of the suture to the tissue it penetrates. Such attachment may make removal of the LS-5™ ePTFE QUICK LOAD® surgical suture difficult and, if attempted, may result in tissue damage.

PRECAUTIONS

- Check for hemostasis or leakage where appropriate.
- Always assure device tip is well visualized before advancing the needle.
- Ensure obstructions do not interfere with movement of the suturing device needle.
- Do not squeeze the lever of the suturing device while loading an LS-5™ ePTFE QUICK LOAD® surgical suture; squeezing the lever may expose the sharp needle and/or damage the needle.
- In handling the suture, care should be taken to avoid jamming the suture into the needle cap compartment and damaging the needle.
- Avoid damage to the needle, suture or needle caps due to direct application of surgical instruments, like forceps, needle holders, clamps, etc.
- Adequate knot security requires accurate completion of accepted surgical techniques for surgically constructed knots.
- Before instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure that mechanical function and electrical isolation and grounding are not compromised.
- Verify that the needle cap is retained within the needle cap compartment and the device has not been damaged or deformed before attempting to place a stitch.
- Do not use damaged suture.
- Store at room temperature. Avoid prolonged exposure to elevated temperatures.

ADVERSE REACTIONS

Adverse effects associated with the use of suture include wound dehiscence, failure of adequate wound support in closure sites where expansion, stretching or distension occur, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, localized irritation when skin sutures are left in place for greater than 7 days, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and pain, edema and erythema. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the country competent authority.

Carefully read and understand the Technology Guides for the related LSI SOLUTIONS® suturing device products prior to using LS-5™ ePTFE QUICK LOAD® surgical suture.

LS-5™ ePTFE sutures differ from and/or exceed USP requirements. See Fig. 2 and Fig. 3 below for LS-5™ suture characteristics.

FIG. 2 Comparison of LS-5™ ePTFE Suture to CV-5 GORE-TEX® Suture			* Per LSI documents and testing. ** Per GORE-TEX® IFU, SEPT. 2023
Property	LS-5™	CV-5	
Knot Pull Tensile Strength (kg)	> 0.60*	> 0.50**	
Average Diameter (mm)	0.305	0.246	

LSI LS-5™ Suture is comparable to GORE-TEX® CV-5 suture. Both LS-5™ and GORE-TEX® CV-5 ePTFE suture are slightly oversized relative to the USP diameter range designation of 0.15-0.199 mm. Of the two only LSI LS-5™ Suture exceeds the minimum knot tensile pull apart parameters established by the USP for 4-0 of 0.60 kg. (FIG.3).

FIG. 3 USP Requirements for Non-Absorbable Suture			
USP Size	Knot Pull Tensile Strength (kg)	Minimum Diameter (mm)	Maximum Diameter (mm)
2-0	1.44	0.30	0.349
3-0	0.96	0.20	0.249
4-0	0.60	0.15	0.199
5-0	0.40	0.10	0.149

FIG. 4 PRODUCT ORDERING			SUPPLIED: STERILE
	REORDER	PRODUCT	DESCRIPTION
 x 12	 022295	LS-5™ ePTFE QUICK LOAD® Suture, Monofilament, Non-Absorbable, 38", 2 Needle Caps	Box of 12 Sutures (1 Suture per Pouch)