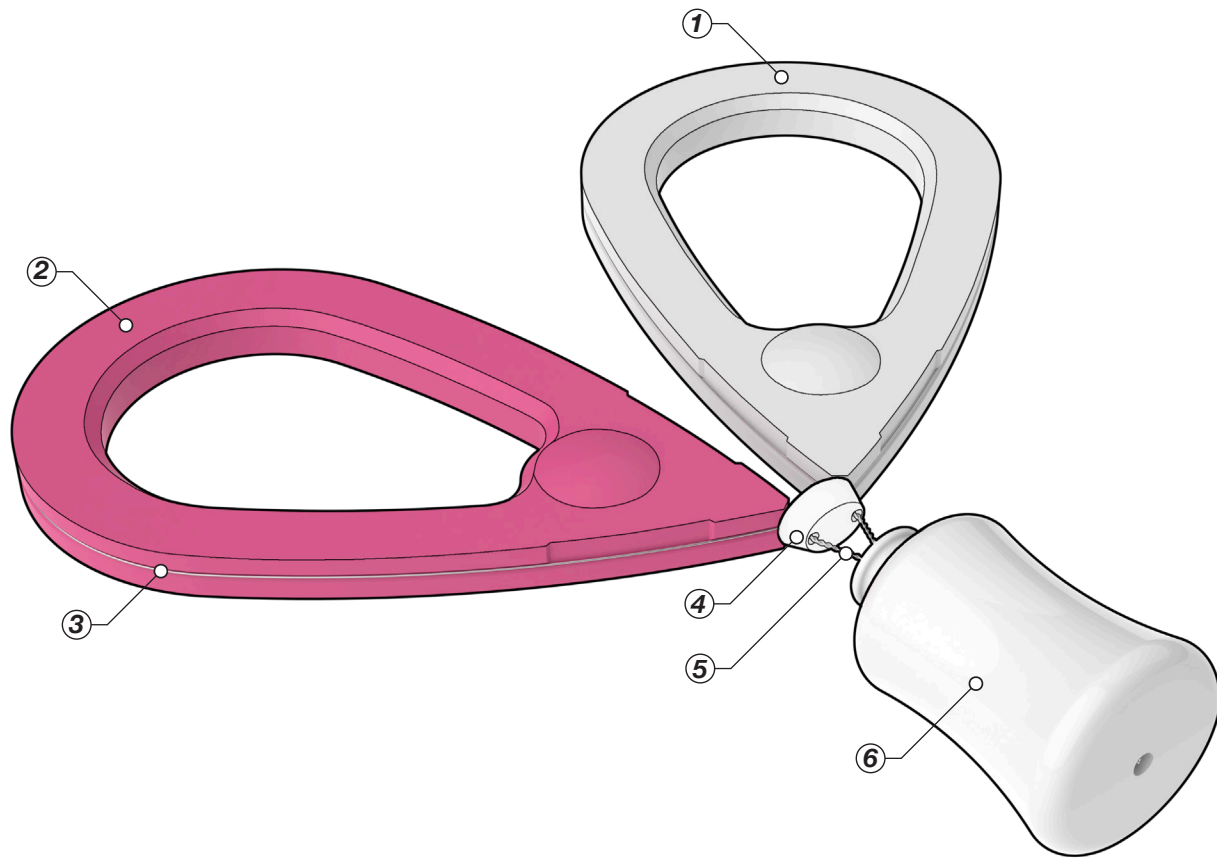


# SVELTEFELT™ QUICK PLEDGE™ UNIT TECHNOLOGY GUIDE

 READ PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1



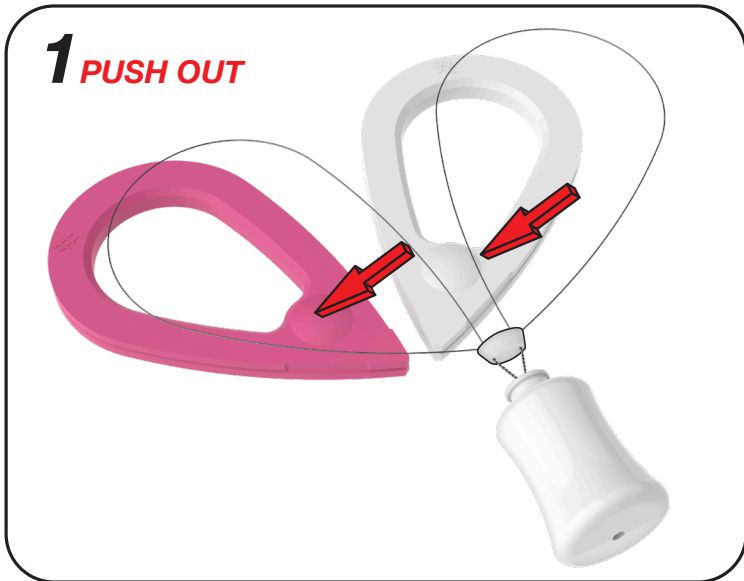
- |                |                 |
|----------------|-----------------|
| ① WHITE TARGET | ④ PLEDGET       |
| ② PINK TARGET  | ⑤ TWISTED WIRES |
| ③ WIRE SNARE   | ⑥ SNARE KNOB    |

## SVELTEFELT™ QUICK PLEDGE™ UNIT DESCRIPTION

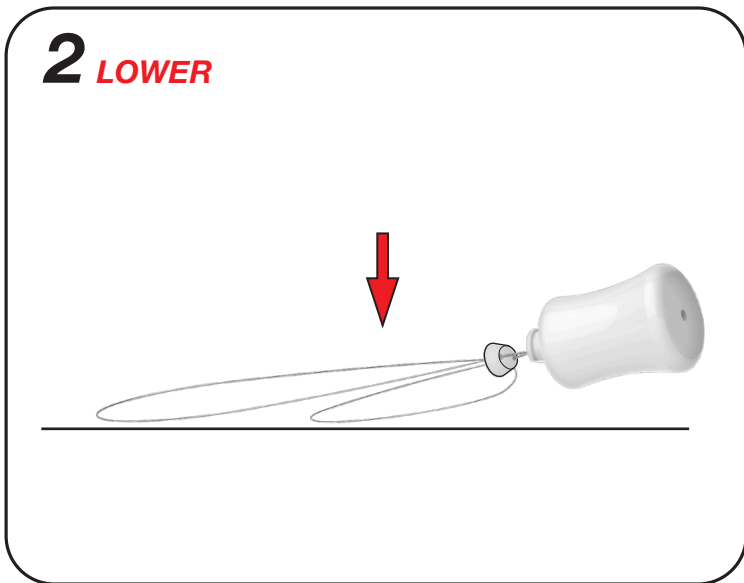
The SVELTEFELT™ QUICK PLEDGE™ UNIT is a sterile, single-use device that facilitates passing both ends of a single surgical suture through 3.5mm spaced holes in a provided PTFE pledget. The SVELTEFELT™ QUICK PLEDGE™ UNIT consists of a white target ① and a pink target ②, each of which is held by a wire snare ③. Each wire snare passes through the respective hole in the PTFE pledget ④. The twisted wires ⑤ connected to each wire snare are connected to the snare knob ⑥. After target removal the ends of a surgical suture are each passed through a separate wire snare, pulling the snare knob draws the snares and suture ends through respective holes in the pledget.

## INDICATIONS

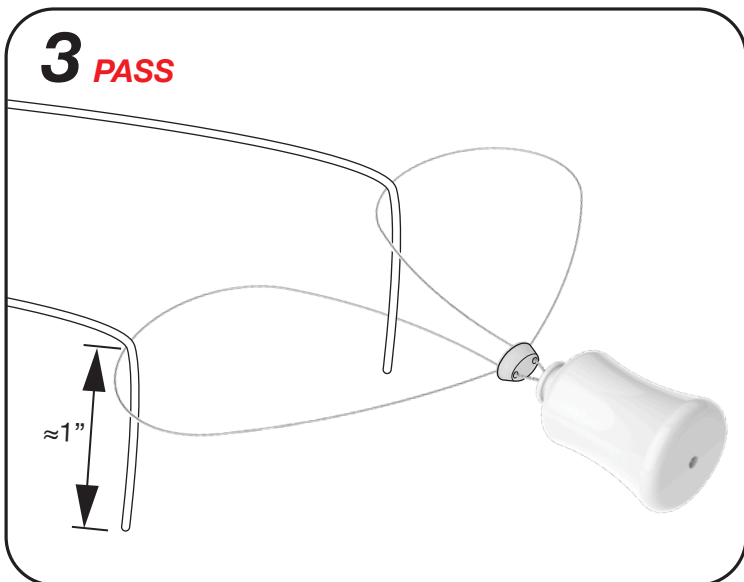
The SVELTEFELT™ QUICK PLEDGE™ UNIT is indicated for use as a suture bolster to assist in the approximation of soft tissue.



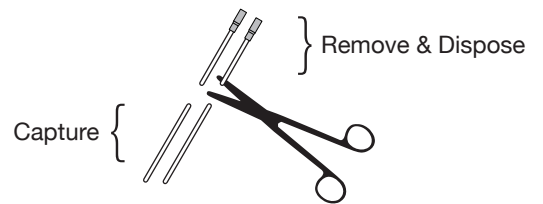
1. **PUSH OUT** and remove the white target and the pink target from the wire snares of the SVELTEFELT™ QUICK PLEDGE™ UNIT.



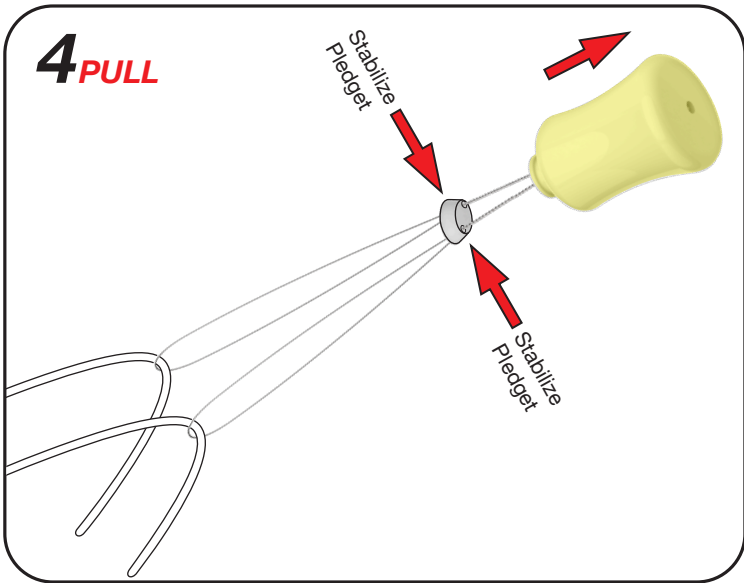
2. **LOWER** the SVELTEFELT™ QUICK PLEDGE™ UNIT wire snares near a sterile surface adjacent to the surgical site to avoid suture falling out of the wire snares.



3. **PASS** about 1–2in (2–5cm) of a single suture end through each of the wire snares.

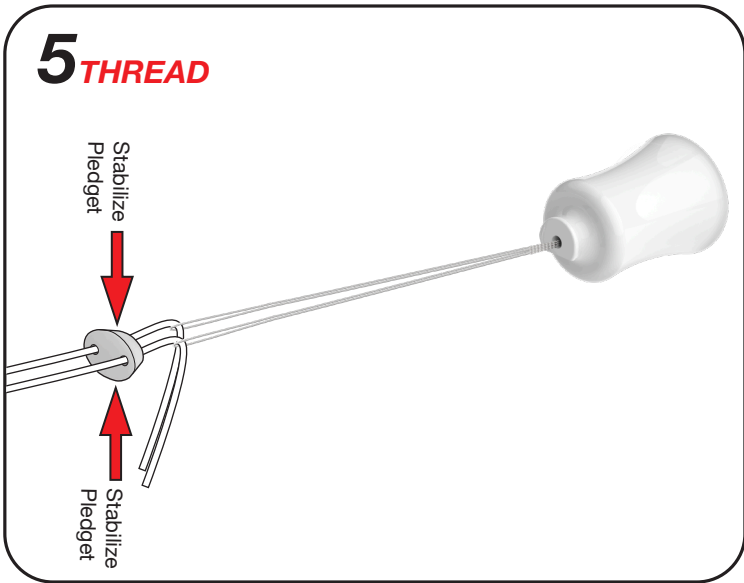


**NOTE:** Ensure that needles or needle caps are removed from the surgical suture and properly disposed of before passing suture through the wire.



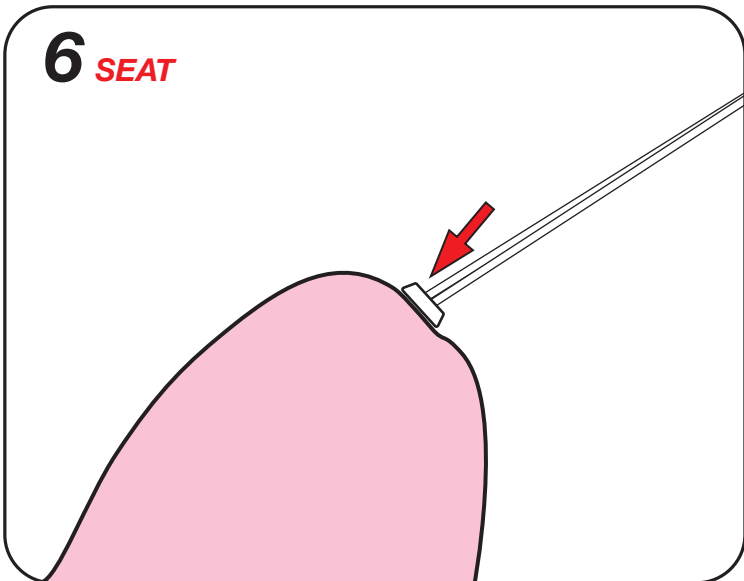
4. **PULL** the snare knob away from the pledget while stabilizing the pledget.

**NOTE:** Ensure the suture ends remain in the snare wires while drawing towards the pledget.



5. **THREAD** to draw the snared suture ends through the pledget while continuing to stabilize the pledget.

**NOTE:** Dispose of the Snare Knob and snare wire after completely drawing the suture through the pledget.



6. **SEAT** the pledget by sliding it down the suture until it is contacting the targeted tissue structure.

**CONTRAINDICATIONS:**

- The SVELTEFELT™ QUICK PLEDGE™ UNIT is contraindicated for use in ophthalmic and neurologic surgery.

**WARNINGS:**

- Federal (U.S.A.) law restricts this device to sale, distribution, and use by, or on, the order of a physician.
- Do not resterilize. The SVELTEFELT™ QUICK PLEDGE™ UNIT is designed and intended for single use only. The performance of the SVELTEFELT™ QUICK PLEDGE™ UNIT after cleaning or other reprocessing has not been verified and is not supported by LSI SOLUTIONS®. Reuse, reprocessing, or reesterilization may compromise the integrity of the devices and/or create a risk of contamination of the devices, which could result in patient injury, illness, or death.
- Discard open (unsealed), unused, expired, or damaged devices or devices in damaged primary packaging.
- Invasive surgical procedures should only be performed by physicians having adequate training and familiarity with open direct visualization or video-enhanced endoscopic techniques. In addition, medical literature should be consulted relative to techniques, complications, and hazards prior to the performance of invasive procedures.
- Do not use the SVELTEFELT™ QUICK PLEDGE™ UNIT under conditions in which excessive suture tension can lead to tissue damage.
- Read and become familiar with all instructions, warnings, and precautions before using this product.
- Acceptable surgical practice and good surgical judgment must be followed with respect to drainage and closure of infected or contaminated wounds.
- Redundant, cut-away suture remnants, used needle caps, and the SVELTEFELT™ QUICK PLEDGE™ UNIT, along with packaging, must be inspected, handled, and disposed of consistent with standard, accepted medical device disposal procedures.
- Applications other than the intended use can result in damage to the device making it unsuitable for continued use.


**PRECAUTIONS:**

- Do not use the SVELTEFELT™ QUICK PLEDGE™ UNIT if it does not satisfactorily perform its intended function or if it has physical damage. Avoid mechanical impact or overstressing the device.
- When handling the SVELTEFELT™ QUICK PLEDGE™ UNIT, care should be taken to avoid damage to the device.
- Check for hemostasis or leakage where appropriate.
- Avoid damage to or dislodgement of the SVELTEFELT™ QUICK PLEDGE™ UNIT pledget due to direct application of surgical instruments, like forceps, needle holders, clamps, etc. If damage is noted, ensure that there are no device pieces, loose targets, or pledget particulate within the surgical field.
- Do not use the SVELTEFELT™ QUICK PLEDGE™ UNIT to dissect or aggressively manipulate tissue structures.
- Surgical instruments may vary in size from manufacturer to manufacturer. Before open surgical or endoscopic instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure that electrical isolation or grounding are not compromised.
- When handling the SVELTEFELT™ QUICK PLEDGE™ UNIT, care should be taken to avoid damage to the pledget. Always inspect the pledget to ensure that it is free of damage after threading the surgical suture.
- Use only with LSI SOLUTIONS® specified 2-0 polyester, 3-0 polypropylene, or LS-5™ ePTFE suture.
- Attempting to reload the device with a new pledget may result in damage to the device.

**ADVERSE REACTIONS:**

- No documented adverse reactions.
- Adverse effects associated with the use of the SVELTEFELT™ QUICK PLEDGE™ UNIT include wound and/or prosthetic dehiscence, failure to provide adequate wound support in closure of sites where expansion, stretching or distension occur, failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from conditions which may delay wound healing enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, localized irritation, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, and pain, edema and erythema at the wound site.

SUTURE COMPATIBILITY TABLE	
SUTURE SIZE AND TYPE	COMPATIBILITY
LSI SOLUTIONS® 2-0 Polyester	✓
LSI SOLUTIONS® 3-0 Polypropylene	✓
LS-5™ ePTFE	✓

FIG. 2 SVELTEFELT™ QUICK PLEDGE™ UNIT PRODUCT ORDERING			SUPPLIED: STERILE
	REORDER	PRODUCT	DESCRIPTION
 x 6	<b>REF 082010</b>	<b>SVELTEFELT™ QUICK PLEDGE™ UNIT</b>	<i>Box of 6 Kits</i>

**LSI SOLUTIONS®**

Patents: [www.lsisolutions.com/patents](http://www.lsisolutions.com/patents)

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