

SUTURE
CONCEPTS™



LEAD
LOOP™
SUTURING
DEVICE

Surgical Technique



INDICATIONS

The LEAD LOOP™ Suturing System is intended for use in securing Spinal Cord Stimulation (SCS) leads and catheters to the fascia or intra-spinous/supra-spinous ligament.

ELEMENTS FOR SECURE FIXATION

The three essential elements for successful Lead Loop use are:

- > Uncompromised fascia (or intra-spinous/supra-spinous) tissue
- > Allowing the suture loop to move freely without restricting or adding friction to the loop in anyway during tensioning
- > Ensuring the anchor is properly set below the fascia tissue layer

SOFT TISSUE MANAGEMENT

An uncompromised fascia layer (or intra-spinous/supra-spinous ligament) is essential to effective use of the LEAD LOOP™ device. Damaged, cut, or otherwise compromised fascia tissue (or intra-spinous/supra-spinous ligament) may lead to additional tissue tearing and impact device performance.



TARGETING TISSUE FOR ANCHORING

- > Quality and security of anchoring will be largely dependent on the quality of tissue targeted for anchor placement
- > Target fascia and tissue that has been uncompromised by cut down, or other dissections during procedure

TIPS, PEARLS AND TROUBLE SHOOTING

NEEDLE INSERTION

- Insert at a 45 degree angle to the tissue surface, and until you feel it penetrate the fascia (or intra-spinous/supra-spinous ligament) layer (going in much deeper adds no benefit)
- Keep device at 45 degree angle until ALL deployment steps are performed
- Remove the inserter at this SAME 45 degree angle

SETTING THE ANCHOR

- With the anchor inserter removed, grasp all the sutures and gently pull them vertically (90 degrees to the patient's spine) until the tissue anchor is seated under the fascia (or supraspinous ligament).
- DO NOT pull at the same 45 degree angle of insertion

- One may feel movement of the PEEK anchor, sensing the anchor is initially migrating through the tissue. This is normal. It will stop when up against the underside of the fascia (or intra-spinous/supra-spinous ligament).

BUTTRESSING THE ANCHOR & TENSIONING THE SUTURE

- Prior to tensioning of suture, ensure sutures are not twisted around each other, as any twists or obstructions increases tension effort
- Ensure the lead anchor is sitting at the base of the loop, a.k.a. the 'V' of the loop
- 'Buttressing' simply means supporting the lead anchor with a Debaquey forceps, at the tissue surface
- When buttressing, it is important to balance providing the appropriate counter force to one's tensioning direction. If too much downward force is applied, pushing the lead anchor into the tissue, it may increase tensioning force required

- Buttressing is also used to control tissue "tenting". Too much "tenting" could lead to insertion hole elongation
- When tightening the suture, gently increase tension forces until the suture loop begins to reduce down around the anchor
- DO NOT use the "grip it and rip it" style of tensioning, as it may compromise the fascia (or intra-spinous/supra-spinous ligament)

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LEAD LOOP™ SUTURING DEVICE

STEP 1 | LEAD LOOP NEEDLE INSERTION

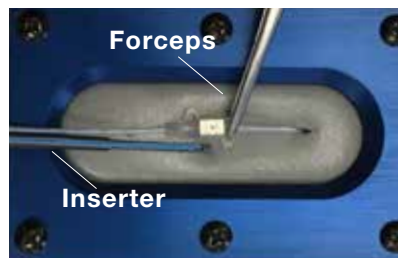


Figure 1a.

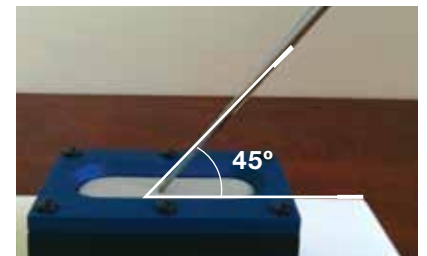


Figure 1b.

- 1a. The tip of the Lead Loop inserter should be placed parallel to the lead anchor, directly next to the lead anchor
- 1b. Insert the Lead Loop shaft at a 45 Degree Angle from the plane of the body direction until you have completely perforated the fascia
- 1c. Leave all suture coiled around the retention sled until after anchor has been deployed

STEP 2 | DEPLOY THE ANCHOR



Figure 2a.

Figure 2b.

Figure 2c.

- 2a. Unlock by lifting knob slightly off 'locking tab'
- 2b. Rotate knob a half-turn (or 180 degrees)—a half turn will align the flat extension of knob with the suture retention sled
- 2c. Depress knob to deploy anchor, ensuring inserter does not move backward upon deployment of anchor

STEP 3 | REMOVING INSERTER

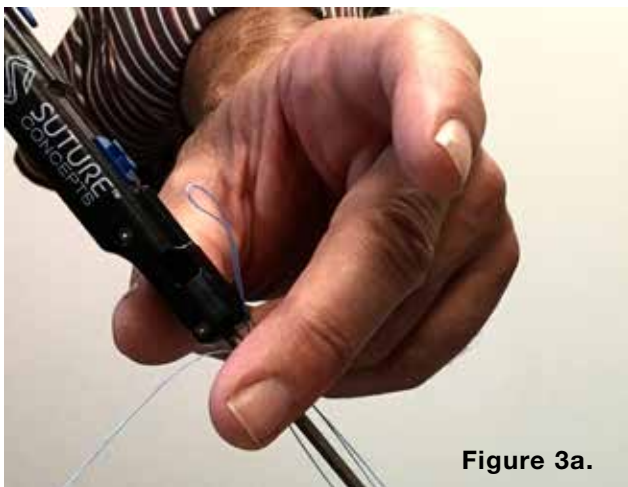


Figure 3a.

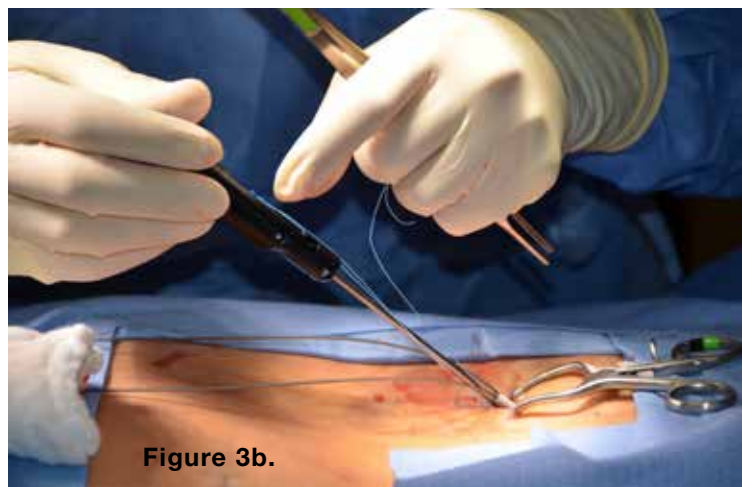
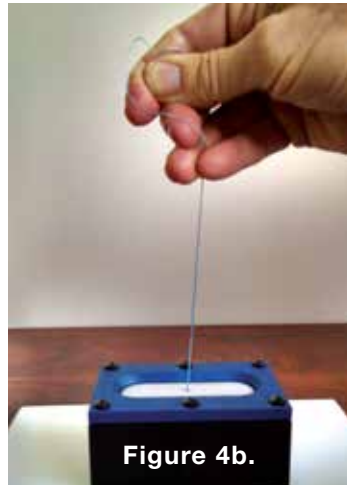
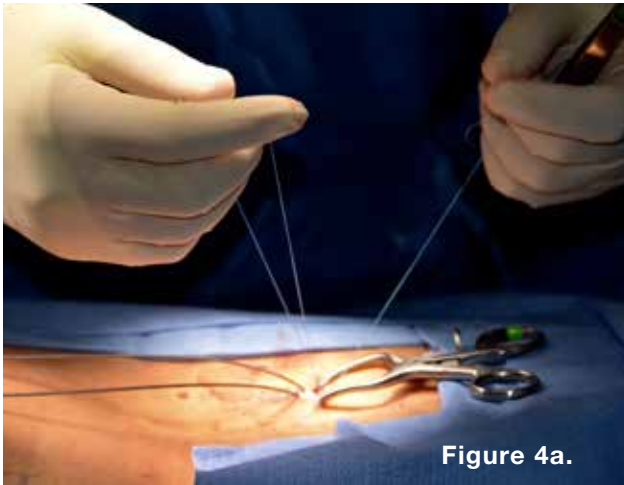


Figure 3b.

- 3a. Remove suture from suture retention sled, and let suture loop and tail lie on either side of incision
Note: if suture is difficult to remove, manually move sled toward patient which will provide slack
- 3b. Remove inserter at same 45 degree angle as inserted (inserter can now be set aside)

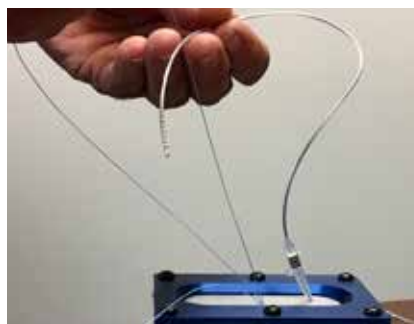
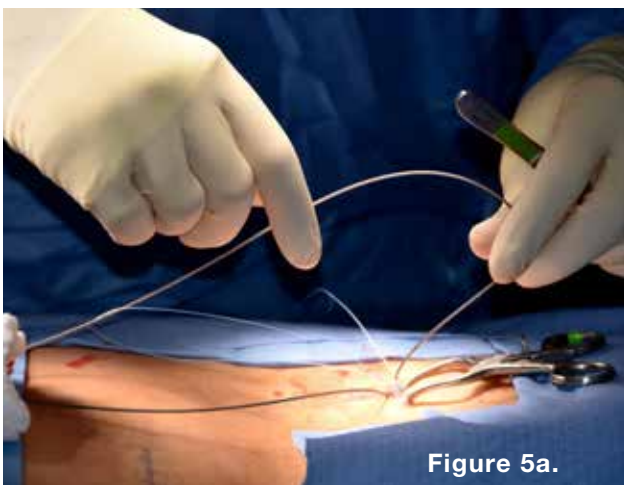
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STEP 4 | SETTING THE ANCHOR



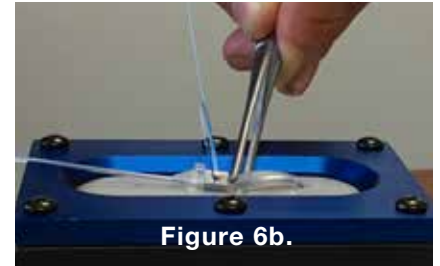
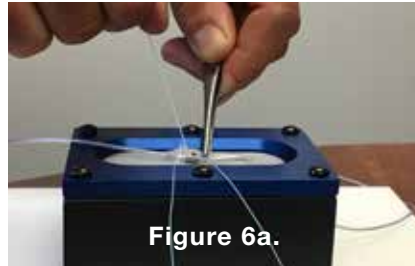
- 4a. Set the anchor by grasping the loop end and tail ends together and lifting straight up, away from patient (perpendicular to patient/spine) **Note:** This ensures anchor has toggled and achieved firm fixation below the fascia
- 4b. Separate loop end and tail end and place on opposite sides of incision

STEP 5 | PLACE SCS LEAD THROUGH SUTURE LOOP



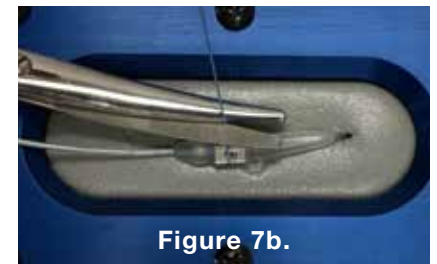
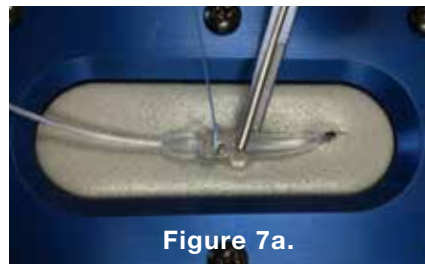
- 5a. Ensure there are no twists in the Suture Loop
- 5b. Thread the free end of the lead through the Suture Loop, and lay the Lead Anchor at the base of the Loop
- 5c. Visually inspect that there are no twists in the suture or obstructions

STEP 6 | BUTTRESS & TIGHTEN THE SUTURE

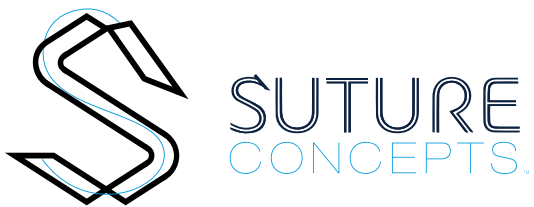


- 6a. Secure the lead anchor with DeBakey forceps (or equivalent), ensuring the forceps are not interfering or grasping the suture in any way
- 6b. The forceps should be used to 'buttress' the lead anchor, in a downward direction towards the patient (or opposite of tensioning force)
- 6c. Ensuring there is no interference to the suture loop, grasp the tail end, and pull straight up in a vertical direction (perpendicular to patient/spine)
- 6d. Continue tightening and approximation of loop around lead anchor until full circumferential capture of lead anchor by the suture is achieved

STEP 7 | CONFIRM POSITION & CUT TAIL



- 7a. Inspect the site to ensure complete and secure capture of the lead anchor
- 7b. When satisfied with the lead anchor suturing, cut the tensioning tail at the level of the lead anchor



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