



## Suture Concepts Inc. White Paper November 22, 2015

Surgical Pearls and Tips  
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Recent advancements in lead anchor technology by the manufacturers of SCS systems have effectively reduced the rate of lead migration in SCS procedures. While the rate of migration has been reduced, I believe that the industry has yet to address the other important step in anchoring leads to the soft tissue.

Anchor site suturing remains a time consuming and often difficult part of the permanent SCS procedure. Lead migration and anchor site pain remain issues even while we see many new technologies emerging to address the ease of lead placement, achieve more effective pain coverage, and employ different power and frequency options.

The Suture Concepts Lead Loop™ represents an important evolution in the advancement of SCS surgery. The Lead Loop™ improves the current surgical technique by achieving secure fixation of the lead and lead anchor to the fascia tissue in a quick and efficient manner. The Lead Loop™ saves time by eliminating the need for suture passing, allows for adjustable tensioning before final fixation, and achieves secure fixation through less invasive incisions. The Lead Loop™ eliminates the need for knot tying and achieves full circumferential capture of the lead anchor of your choice.

I have been using the Lead Loop™ in my practice since its launch on September 1, 2015. Being the first physician to use the device, I have had a unique opportunity to help define the practical surgical procedure for the device. I have found that as with any device, there are certain steps that are required to make the device most effective in the procedure.

Below I outline the steps of my procedure and add some commentary to those steps I have found to have the greatest impact on securing the lead anchor to the tissue. Note that it is always important to follow the Directions for Use from the manufacturer.

### **Suture Concepts Lead Loop Procedural Steps**

1. Placement of the tip Lead Loop inserter should be parallel to the lead anchor directly next to the lead anchor, leave all suture coiled around the retention sled until after the Lead Loop anchor has been inserted.
2. Penetrating the fascia should be done at a ~45 degree angle from the plane of the body. This technique ensures that when you set the tissue anchor, you are doing so at a different angle from insertion.
3. The plunger knob should be held firmly in place while inserting the tip of the inserter into the fascia
4. Insert the shaft in either a caudal or cephalad direction until you have completely perforated the fascia.



5. Unlatch the plunger gate and depress the plunger knob completely ensuring the inserter instrument does not migrate backward.
6. Push suture sled forward completely so that the suture is loose and can easily be removed from the cleat on the sled.
7. Remove the suture tail and loop and remove the inserter and separate the loop from the tensioning tail.
8. Grabbing the full loop, pull up in a vertical (perpendicular to the spine) direction to ensure the anchor has toggled beneath the fascia, setting the Lead Loop anchor and achieving solid tissue fixation.
9. Ensure there are no twists in the loop, then thread the free end of the lead through the loop and lay the loop to the side of the incision.
10. Secure the lead anchor with instrumentation or fingers. Take up the tensioning suture strand and pull up in a vertical direction, similar to setting the Lead Loop anchor, in a slow steady motion. Be sure not to add interference or friction to the loop while tensioning it around the lead anchor. Any friction or interference with fingers or instrumentation can increase tensioning forces required to reduce the loop.
11. Tension the suture until the loop fully and securely captures the lead anchor and snugs it down onto the tissue in the incision.
12. Check the lead end to ensure secure capture of the lead anchor. If further tensioning is desired, repeat step 11 until the desired tension is achieved
13. When satisfied with the lead anchor suturing, cut the tensioning tail at the level of the lead anchor

### **About Lead Loop™**

The Suture Concepts Lead Loop™ suturing device is intended for use in securing Spinal Cord Stimulation (SCS) leads and catheters to the fascia or intra-spinous/supra-spinous ligament.

The Lead Loop™ tissue anchor contains a knotless suture retention system that allows for circumferential capture of the lead anchor with a simple tensioning technique. The device eliminates the need for multiple suture passes and needle management that comprise the traditional lead anchor suturing techniques. Additionally, the Lead Loop™ eliminates knot tying and the inherent loosening of fixation through knot creep. The Lead Loop™ provides more consistent and secure tissue fixation and lead capture while minimizing the incision size at the anchoring site.

### **About Suture Concepts Inc.**

Suture Concepts exists to provide simple and effective solutions to physicians who practice in a cost conscious environment. Leveraging our experience in medical device development and operational efficiency allows us to deliver cost appropriate, innovative, and novel solutions to surgeons and physicians. Suture Concepts' expertise are focused on employing solutions to securing soft tissue to other tissue, to bone, or to medical devices. Our combined years in medical devices, in particular sports medicine, development gives us a unique perspective on soft tissue approximation problems in all areas of medicine.

Suture Concepts is a venture capital backed early stage medical device company with offices in Basking Ridge, NJ and Beverley, MA.