SUTURE CONCEPTS™
Lead Loop™ Suture Anchor
CAT-LLSD10, CAT-LLSD20,

Please read this information carefully before using the Suture Concepts™ (S.C.) Lead Loop™ Suture Anchor.


Important Safety Information Follows


Single Use, Do Not Reuse


Do Not Use if Package is Damaged


Use by Date

Sterilized by Ethylene Oxide

R_x Only

PRODUCT DESCRIPTION

The Suture Concepts™ Lead Loop™ Suture Anchor is a singular anchor threaded with an adjustable loop of non-absorbable size 0 suture. The suture material is ultra-high molecular weight polyethylene. The anchor is composed of carbon fiber reinforced polyetheretherketone (PEEK-OPTIMA®). PEEK-OPTIMA® is a registered trade mark of INVIBIO®. The product is provided sterile and pre-loaded in a needle tipped disposable delivery tool to facilitate insertion into tissue.

MATERIALS

CAT-LLSD10

Implant: Implant Grade Carbon Filled Polyetheretherketone (PEEK), PEEK OPTIMA® by Invibio® , UHMWPE size 0 braided polyethylene suture.

Inserter: Surgical grade stainless steel and ABS, Polycarbonate or ABS/Polycarbonate blended plastic.

CAT-LLSD20

(2) Implants: Implant Grade Carbon Filled Polyetheretherketone (PEEK), PEEK OPTIMA® by Invibio® , UHMWPE size 0 braided polyethylene suture.

(2) Inserters: Surgical grade stainless steel and ABS, Polycarbonate or ABS/Polycarbonate blended plastic.

INDICATIONS

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

CONTRAINDICATIONS

The product is intended for use only as indicated.

ADVERSE EFFECTS

1. Infection, both deep and superficial.
2. Allergic reaction to product materials. Patient sensitivity to product materials must be considered prior to implantation.
3. Acute inflammatory response.
4. Wound dehiscence.

WARNINGS

This product should only be used by physicians with training in and a thorough understanding of the indicated surgical procedures.

1. Use only the suture that is provided with the S.C. Lead Loop™ Suture Anchor.
2. The S.C. Lead Loop™ Suture Anchor must be used only with the inserter provided
3. Incomplete insertion may result in a product failure.
4. Product materials may cause allergic reactions including, but not limited to, foreign body reaction, tissue irritation/inflammation or other allergic reactions. Where material sensitivity is suspected, appropriate tests should be made and sensitivities ruled out prior to use.
5. The product is sterile unless the package is damaged. Discard any open unused products.
6. Do not use beyond the expiration date listed on the label. The performance, safety, and/or sterility of the product cannot be assured beyond the expiration date.
7. Do Not Re-sterilize. Single Use Only. The ability to effectively clean and re-sterilize this single use product has not been established and subsequent re-use may adversely affect the performance, safety and/or sterility of the product.
8. Do not use if conditions exist that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.

PRECAUTIONS

Special attention and operator judgment should be exercised in the following situations.

1. Pathological conditions in the tissue that could adversely affect suture fixation.
2. Physical conditions that would eliminate, or tend to eliminate, adequate implant support or retard healing.
3. Blood supply limitations and previous infections that may retard healing.
4. The S.C. Lead Loop™ Suture Anchor has not been evaluated for safety and compatibility in the MR environment. The S.C. Lead Loop™ Suture Anchor has not been tested for heating or migration in the MR environment.

PREPARATION FOR USE

1. Inspect for damage to product or sterile barrier. Do not use if the product is damaged or the sterile barrier is compromised.
2. Remove the product from the packaging and carefully slide the protective tubing from the shaft of the delivery tool.
3. Users of this product are encouraged to contact their Suture Concepts™ representative if, in their professional judgment, they require more comprehensive explanation of the technique to be used with the product.
4. Prior to introducing the product, ensure that the desired insertion location does not contain nerves or blood vessels.

DIRECTION FOR USE

1. With the desired suturing location determined, press the needle tip of the insertion tool through the tissue at a 45 degree angle until it occludes the fascia or intra-spinous/supra-spinous ligament.
2. Disengage the Plunger stop finger from the handle by moving it proximally until the knob finger and the tab on the handle are no longer engaged, rotate the knob one half turn and depress the plunger knob completely until it makes contact with the handle body.
3. Release the suture loop and suture tension tail from the suture retainer on the inserter handle.
4. Remove the insertion tool from the tissue and lightly pull on the suture loop and suture tension tail individually to test that the anchor is secured under the fascia or intra-spinous/supra-spinous ligament and any slack suture beneath the fascia or intra-spinous/supra-spinous ligaments is taken up.
5. Separate the suture loop from the single suture tail.
6. Pass the Spinal Cord Stimulation lead or Catheter through the loop and position as necessary for proper function according to lead / catheter manufacturer instructions.

7. Prior to final tightening of the suture loop around the lead or catheter, ensure the SCS tip or Catheter positions are correct.
8. To finish tightening the suture loop around the lead/catheter, support the top of the lead / catheter anchor on top of the suturing location and gradually pull on the tension tail until the suture begins to move through the anchor. Continue pulling the suture tail until the suture loop is tight around the lead / catheter anchor.
9. Trim the excess suture on the tension tail suture.

HOW SUPPLIED

The Suture Concepts™ Lead Loop™ Suture Anchor package supplies the user with an Anchor preloaded with USP Size 0 UHMWPE suture, pre-mounted in a single-use, disposable insertion tool. All components are provided sterile (Ethylene Oxide) for single patient use only. Do not re-sterilize.

STORAGE AND HANDLING

Store in a cool, dry place and in a manner that protects the integrity of the package and sterile barrier. The product should not be used after the expiration date.

CAUTION: Federal law (USA) restricts this product to sale by or on the order of a physician.

Manufactured for Suture Concepts, Inc.

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Patent: US 9,949,734 and other Pending Patents apply.