Evoke® SCS System Surgical Guide

Instructions for the use and implantation of the Evoke SCS System

Rx Only

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Trademarks

Refer to the Evoke SCS System Clarity Clinical Manual for:

- Instructions on the use of the Evoke Clinical Interface and the Evoke Clinical System Transceiver.
- Instructions on programming the Evoke SCS System.

Refer to the Evoke SCS System User Manual for:

- Instructions on the use of the Evoke Patient Controller (EPC) and Evoke Charger.

Manuals are accessible at http://www.saludamedical.com/manuals.

1 Description

The Saluda® Medical Evoke® SCS System is a Spinal Cord Stimulation (SCS) system that incorporates ECAP-controlled closed-loop stimulation for the management of chronic, intractable pain. The Evoke System measures evoked compound action potentials (ECAPs) and may be programmed to deliver either ECAP-controlled closed-loop SCS or fixed-output open-loop SCS.

The Evoke Clinical Interface (CI) and Evoke Clinical System Transceiver (CST) enable the programming of the implantable Closed-Loop Stimulator (CLS) and the non-implantable external Closed-Loop stimulator (eCLS), which deliver therapy to the spinal cord through the Evoke CAP12™ Percutaneous Leads and Lead Extensions (if used).

The Evoke System may be used in conjunction with other pain management therapies, as determined by the physician.

1.1 The concept of ECAP-controlled closed-loop SCS

The Evoke System uses ECAP amplitude to measure the patient's neural response and provide closed-loop (CL) SCS. The ECAP amplitude is a measure of the spinal cord activation or number of dorsal column fibers in the spinal cord that are activated by a stimulation pulse. When closed-loop is enabled, the system automatically varies the stimulation current for every pulse to maintain consistent spinal cord activation during physiological changes and movement.

Figure 1.1, below, depicts the concept of an ECAP-controlled closed-loop system. Following a stimulation impulse, the amplitude of the ECAP that is generated in the spinal cord by that stimulus is recorded. The ECAP amplitude is compared to the selected target and then used to automatically adjust the current of the next stimulus to maintain a consistent ECAP amplitude.

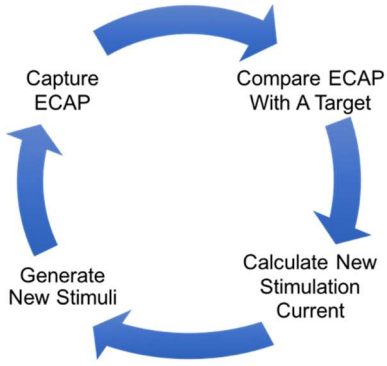


Figure 1.1: ECAP-Controlled Closed-Loop SCS.

1.2 System Components

1.2.1 Evoke Closed-Loop Stimulator (CLS)

Ref No. 3042

The Evoke Closed-Loop Stimulator (CLS) is a totally implanted spinal cord stimulator that connects to the CAP12 Percutaneous Leads and is implanted under the skin for long-term therapy. The CLS delivers either closed-loop or open-loop stimulation through the leads and measures the neural response to stimulation. A port plug is provided with the CLS, for insertion into an unused CLS port when only one lead is implanted.

1.2.2 Evoke External Closed-Loop Stimulator (eCLS)

Ref No. 3036

During the trial stimulation period, the CAP12 Percutaneous Leads are connected to the Evoke External Closed-Loop Stimulator (eCLS). The eCLS is an external stimulator used for intraoperative testing and during the trial stimulation period. The eCLS delivers either closed-loop or open-loop stimulation through the leads and measures the neural response to stimulation.

1.2.3 Evoke eCLS Case

Ref No. 3035

The Evoke eCLS Case is used by the patient to house the eCLS during the trial stimulation period. The kit also includes two lead adapters to connect the leads or lead extensions to the eCLS

1.2.4 Evoke CAP12 Percutaneous Lead Kit, 60cm and 90cm

Ref No. 3008/3016/3009/3017

The Evoke CAP12™ Percutaneous Leads are placed in the epidural space overlying the spinal cord and are connected to an eCLS for a trial stimulation period, or to a CLS for long-term therapy. One or two leads, each with 12 electrodes, are implanted. The lead kit is provided with one suture anchor to secure the lead, and surgical accessories (epidural needle and two stylets) for use during lead placement.

1.2.5 Evoke CAP12X Lead Extension Kit, 55cm

Ref No. 3011

The Evoke CAP12X™ Lead Extensions are required when the implanted lead does not reach the CLS pocket, or when trialing a permanently implanted lead, when an extension is externalized for connection to an eCLS.

1.2.6 Evoke Active Anchor Kit

Ref No. 3043

The Evoke Active Anchor allows the surgeon to secure the lead after placement in the epidural space. The active anchor kit is provided with two active anchors and a torque wrench to tighten the anchor.

1.2.7 Evoke Intraoperative Cable Kit

Ref No. 3034

The Evoke Intraoperative Cable allows the surgeon to connect the eCLS to the implanted leads for intra-operative testing.

1.2.8 Evoke Tunneler

Ref No. 3012

The Evoke Tunneler allows the subcutaneous threading of leads and/or lead extensions, either to an exit incision for the trial stimulation period, or to the CLS.

1.2.9 Evoke Spares Kit

Ref No. 3015

The Evoke Spares Kit contains all items from the permanent lead kits except for the lead itself, plus a CLS port plug and torque wrench. The Evoke Spares Kit will save surgeons from opening a new lead kit should any of the small accessory items be dropped or damaged during the procedure.

1.2.10 Epidural Needle 6.5”

Ref No. 3014

The 6.5” Epidural Needle Kit is an optional long needle for larger patients in whom the regular 4.5” needle supplied with the lead kits is too short to reach the epidural space.

2 Indication for use

The Saluda Medical Evoke SCS System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

3 Contraindications

The Evoke SCS System should not be used in patients who:

- Do not receive effective pain relief during trial stimulation
- Are unable to operate the Evoke SCS System.
- Are unsuitable surgical candidates.

4 Safety information

For warnings and precautions associated with the Clinical Interface (CI), Clinical System Transceiver (CST) and associated programming, please refer to the Evoke SCS System Clarity Clinical Manual, accessible at http://www.saludamedical.com/manuals.

Patients must be advised of the following warnings and precautions (Sections 4.1 and 4.2).

4.1 Warnings

⚠ Diathermy

- Patients implanted with the Evoke System should not be subjected to shortwave, microwave and/or therapeutic ultrasound diathermy.
- Diathermy generates energy that may cause heating at the lead site, resulting in damage to the CLS, tissue damage, severe injury, or death.

⚠ Magnetic Resonance Imaging (MRI)

- As the Evoke System has not been tested for MRI compatibility, it is considered MR Unsafe.
- Patients implanted with the Evoke System should not be subjected to MRI as it may result in significant heating and/or tissue damage.
- MRI exposure can damage the CLS, potentially requiring device explantation and replacement.
- MRI exposure may also induce currents through the leads and stimulator leading to

unintended stimulation, such as tingling, shocking, or jolting.

⚠ CT Scans

- Patients implanted with the Evoke System may experience a momentary increase in stimulation when receiving a CT scan. Some patients have described this as uncomfortable stimulation, jolting, or a shocking sensation.
- Prior to a patient undergoing a CT scan, turn the stimulator off.

⚠ Electrosurgery

- Patients implanted with the Evoke System should not be subjected to electrosurgical techniques, such as electrocautery, in close proximity to the Evoke System components.
    - Electrosurgical devices generate energy that may cause tissue damage at the lead site and result in severe injury.
    - Damage may also occur to the CLS.
- If the patient is required to undergo electrosurgery, minimize the energy that may affect the Evoke System:
    - Turn off stimulation.
    - Disconnect the eCLS if this is in use.
    - Ensure all fields, electrodes, probes and/or ground plates are as far away as possible from the Evoke System.
    - Use the lowest energy setting needed for the therapy.
    - Check the functioning of the Evoke System after the procedure and contact Saluda Medical if any problems are apparent.
    - Use bipolar mode if available.

⚠ Interference with implanted cardiac devices

- The Evoke System may interfere with other implanted stimulators with sensing capabilities, such as demand type pacemakers or cardioverter defibrillators.
- The effects of implanted stimulation devices on the Evoke System is unknown.

⚠ Stimulator damage

- If the CLS case is ruptured or pierced, then patient tissue may be exposed to battery chemicals, which could lead to burns or tissue damage.
    - Do not implant the CLS if the case is damaged.

⚠ Electromagnetic interference

- Strong electromagnetic fields may turn the stimulator off, cause uncomfortable or

jolting stimulation or affect communication with the EPC.

- Patients should be advised to avoid or turn stimulation off around:
    - Security screeners, such as those used at department stores, public buildings, and airports – patients should present their implantable device ID card and request to go around the screener. If they are required to go through the screener they should turn stimulation off.
    - Power lines or power generators.
    - Electric steel furnaces and arc welders.
    - Large, magnetized stereo speakers.
    - Tag deactivators, such as those found in retail stores and libraries.
    - Radio communication transmitters or antennas, such as CB radio antennas (see Section 17.4).
- Patients should be advised to seek medical advice before entering any environment that may adversely affect the operation of their stimulator, including areas protected by a warning notice preventing entry by patients fitted with a pacemaker.

⚠**Heat due to charging**

- During charging, the Charger, Charger coil, and/or CLS may become hot.
- Patients should not charge while sleeping, or with the Charger coil wrapped in blankets or clothing for prolonged periods, as this may result in heating leading to redness, skin irritation, or a burn.
- Patients should ensure there are no metal objects between the Charger coil and the stimulator during charging, as the metal object may heat up and cause redness, skin irritation, or a burn. Additionally, the Charger may not operate correctly.
- The Charger unit may become hot during use, with a surface temperature reaching 48 °C (118 °F). Patients should be advised not to hold the Charger unit for longer than 10 minutes during use to prevent risk of skin irritation, redness or injury.
- If patients experience pain or discomfort, they should cease charging and contact Saluda Medical.

⚠**Allergic reaction to system components**

- If the patient may be allergic to system components they should not be implanted.
- Please refer to Section 17 for a list of materials in the system.
- Contact your Saluda Medical Representative for more information if necessary.

⚠**The Evoke System has not been tested for use in patients who are pregnant or nursing.**

⚠**The Evoke System has not been tested for use in patients under 18 years old.**

4.2 Precautions

⚠**Physician training**

- Implanting physicians should be trained in SCS procedures.
- Physicians should review this surgical manual before surgery.

⚠**Medical imaging**

- MEG, PET, x-ray/fluoroscopy and diagnostic ultrasound are unlikely to affect the Evoke System.

⚠**Medical therapies**

When used in close proximity to the Evoke System, the following medical therapies may turn stimulation off or cause damage to the CLS:

- Ultrasonic scanning
- High-output ultrasound
- Lithotripsy

Implanted parts of a system should not be exposed to therapeutic levels of ultrasound energy as the implantable parts can inadvertently concentrate the ultrasound field and cause harm.

- Electrocautery or electrosurgical diathermy
- External defibrillation
- Radiation therapy (any damage to the device by radiation may not be immediately detectable)
- TENS
- Psychotherapeutic procedures (e.g. electroconvulsive therapy, transcranial magnetic stimulation)
- Laser procedures

If the patient is required to undergo any of these therapies, minimize the energy that may affect the Evoke System:

1. Turn off stimulation.
2. Disconnect the eCLS if this is in use.
3. Ensure all fields, electrodes, probes and/or ground plates are as far away as possible

from the Evoke System.

4. Use the lowest energy setting needed for the therapy.
5. Check the functioning of the Evoke System after the procedure and contact Saluda Medical if any problems are apparent.
6. Use bipolar mode if available.

⚠ Operating equipment

The Evoke System is an SCS system that measures the patient's Evoked Compound Action Potentials (ECAP) in response to stimulation and adjusts the amplitude of stimulation in order to maintain stable coverage of painful areas. This is known as ECAP-controlled closed-loop stimulation.

- If the Evoke System has closed-loop stimulation enabled, patients may leave stimulation on while operating automobiles, other vehicles, or potentially dangerous equipment.
- During charging closed-loop is disabled, so patients should turn stimulation off if charging while driving or operating equipment.
- If the patient experiences sudden changes in stimulation with closed-loop enabled, they should turn stimulation off before driving or operating equipment. In this case, the patient should contact the clinic to reprogram the closed-loop settings of the stimulator.

When operating with closed-loop stimulation disabled, the Evoke System may produce sudden changes in stimulation that may distract patients while driving or operating equipment.

- If the Evoke System has closed-loop disabled, patients should turn stimulation off before operating automobiles, other vehicles, or potentially dangerous equipment.

⚠ Post-operative patient instructions

- After implantation of the Evoke System, patients should take care to allow adequate healing and ensure that the leads and CLS do not move.
- For six to eight weeks after surgery, patients should avoid:
    - lifting more than 11 lbs. (5 kg);
    - physical activities requiring stretching, bending or twisting;
    - raising their arms above their head repetitively.
- Patients may experience temporary pain at the implant site as the incisions heal after the surgery.
- Patients may experience redness or irritation at the implant site, in which case they should contact their physician to check the wound for infection or adverse reaction to the implanted materials.

⚠ Stimulator manipulation

- Patients should avoid manipulating the Evoke System through the skin. This may cause damage to the system, which could stop therapy, and may require surgery to rectify. Such manipulation of the device could also lead to painful tissue damage or skin erosion.
- If the CLS is “flipped” over inside the skin pocket it may no longer be able to be charged.

⚠ Scuba diving

- Patients should always obtain advice from their clinician prior to any diving activities.
- Patients should not dive below 16 ft. (5 m) or use hyperbaric chambers above 1.5 atm (150 kPa).
- The CLS may be damaged at greater depths or pressures.

⚠ Sterilization, storage and operation

- All surgical and implantable components of the Evoke System are supplied sterile.
- The sterile components of the Evoke System are sterilized using ethylene oxide.
- All sterilized components of the Evoke System are single use only, and should not be re-sterilized or reused, because of the risk of infection and device malfunction.
- Please observe and use infection control procedures of the accredited site where procedure is being performed.
- Please observe the storage conditions printed on the labels of each component – particularly storage and transport temperature and humidity, which varies between components – as inadequate storage could have a negative impact on operation, shelf-life and sterility.
- Please observe the expiration dates printed on the labels and return any expired product to Saluda Medical because of the risk of infection.
- Do not use surgical or implantable components if the package appears to be damaged or has been previously opened. If the packaging appears to be damaged, please return it to Saluda Medical for replacement.
- Visually inspect the stainless-steel components of the device for evidence of rust prior to use. If any rust (corrosion) is visible, the devices should be discarded.
- All sterile products are packaged in an outer sealed tray or pouch and should be opened with care to maintain sterility of the contents. The sterile contents of the tray or pouch should only be handled inside the sterile surgical field.
- The CLS is packaged in an inner and outer tray. Only the outer tray is the validated sterile barrier and therefore the inner tray should not be placed back into storage once it is taken out of the outer tray.
- Handle system components carefully to protect them from striking hard surfaces or being dropped.

- Do not use system components if they appear damaged, broken or malfunctioning as this may result in electrocution or excess heat generation causing burns or tissue damage.
- Stop using the eCLS if it becomes warm during use.
- Do not get the eCLS wet.
- Patients should be advised to avoid storing or using the Evoke external accessories outside the labeled temperature ranges or in hot or steamy environments, such as bathrooms, and to keep them dry.
- Patients should be advised to refer to the Evoke SCS System User Manual for guidelines for safe use of batteries in the Evoke System.

⚠ Modifications to System

- The components of the Evoke System are not intended to be modified by users or surgeons in any way.
- Do not modify or tamper with the Evoke Patient Controller (EPC), the Charger or the external Closed-Loop Stimulator (eCLS). Modifying or tampering with system components could cause malfunctions, unpredictable device behavior or failure, leading to harm to the patient.
- Do not connect anything to the eCLS or Charger that is not supplied as part of the Evoke System. The eCLS should only be connected to intraoperative cables or lead adapters by the clinician
- The Charger should only be connected to the supplied power adapter. Connecting these devices to other, unsupported items could damage them and lead to a loss of therapy.
- Only use the supplied eCLS battery and only charge the eCLS battery with the supplied eCLS battery charger. Refer to the Safety Precautions sheet provided with the eCLS battery charger.
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ Protection of external system components; eCLS, EPC and Charger

The electronics in external devices in the Evoke System such as the eCLS, Charger and, EPC, can be damaged by moisture, extreme heat, cold and humidity.

- Avoid storing the eCLS at temperatures below -10°C (14 °F) or above 55 °C (131 °F).
- Avoid storing the EPC and Charger at temperatures below -20 °C (-4 °F) or above 60 °C (140 °F).
- Only use the eCLS and EPC at room temperatures of 5 °C (41 °F) to 40 °C

(104 °F).

- Only use the Charger at room temperatures of 5 °C (41 °F) to 30 °C (86 °F). Do not use the Charger if the room temperature is above 30 °C (86 °F).
- The eCLS is not moisture resistant whilst the case is open. Take care that the eCLS does not come into contact with liquids whilst the case is open. Wetting of the eCLS whilst out of its case may cause device malfunction or failure, leading to ineffective therapy for the patient.
- External system components should be kept dry and never be immersed in water.
- Handle external system components carefully to protect them from striking hard surfaces or being dropped.
- The Charger should not be plugged into outlets that are in humid environments or near water.
- The Serial connection  on the Charger is for Saluda Medical representative use only. This connection is protected by a silicone plug. Ensure the plug is fully inserted at all times.
- Instruct patients not to leave devices in their car or outdoors for extended periods of time.
- Instruct patients not to store devices in humid environments, such as the bathroom.
- Instruct patients to allow devices to reach room temperature for 30 minutes before use if they have been stored in cold or warm conditions.
- Instruct patients to ensure they can always access their EPC and to keep a spare set of AAA batteries at home for the EPC.
- Instruct patients to plug in the power adapter for the Charger somewhere easy to access.
- If any external system components require cleaning, refer to Section 15 ‘Maintenance of the Evoke eCLS, EPC, and Charger’.

⚠ Battery care

The EPC is powered by two disposable AAA alkaline batteries. Observe the following guidelines for safe use of batteries with your EPC:

- Insert batteries in the correct orientation by observing the plus (+) and minus (-) marks on the batteries and the EPC.
- Do not mix batteries that differ by manufacturer, brand, type, age or previous usage.
- Replace both batteries at the same time.
- Do not touch the battery contacts in the EPC.
- Do not short-circuit batteries (e.g. do not let terminals of batteries contact each other,

do not store batteries loosely).

- Do not disassemble, deform, immerse in water, or dispose of batteries in fire.
- Wipe batteries with a clean dry cloth if they become dirty.
- Store unused batteries in original packaging, in a clean and dry place.
- Do not use damaged or deformed batteries. If skin or eyes come into contact with battery fluid or liquid, wash out with water and seek medical attention immediately.
- Do not expose batteries to heat.
- Do not recharge batteries.
- Dispose of used batteries promptly and carefully, in accordance with local regulations. Keep away from children.

The Charger is powered by internal rechargeable lithium ion batteries that cannot be replaced:

- Only the power adapter supplied by Saluda Medical should be used to recharge the Charger.
- The power adapter socket on the Charger should not be touched.
- The Charger power adapter should be unplugged from the charger after recharging is complete.

The eCLS is powered by a rechargeable, replaceable lithium ion battery:

- Only the supplied battery should be used to power the eCLS.
- Only the supplied eCLS battery charger should be used to recharge the eCLS battery.
- Do not cover the eCLS battery or charger whilst recharging the battery.
- Avoid the eCLS battery being dropped or striking hard surfaces. Damage to the eCLS battery could cause leakage, overheating or explosion.
- Do not use the eCLS battery if it is damaged or deformed. If skin or eyes come into contact with battery fluid or liquid, wash out with water and seek medical attention immediately.
- Do not disassemble, deform, immerse in water, or dispose of eCLS battery in fire.

⚠ Device malfunction or failure

Therapy should be discontinued immediately in the event of malfunction or failure of any component of the Evoke system.

- Malfunction or failure may be indicated by excessive device heating, emission of smoke or strange smell, or abnormal device behavior.
- Continued use of system components after malfunction or failure may cause electrocution, burns, tissue damage or uncomfortable stimulation for the patient.

- Please contact Saluda Medical in the event of any device malfunction or failure.

⚠ Disposal of Evoke System Components

- Do not dispose of the CLS, eCLS, EPC or Charger devices. These devices contain batteries that could explode if they are thrown into a fire.
- All explanted, malfunctioning or failed Evoke devices should be returned to Saluda Medical.

4.3 Potential risks

Every surgery involves potential risks, including death. In addition to these surgical risks, the risks associated with the implantation and use of a spinal cord stimulation system include:

- Undesirable changes in stimulation sensation and/or location.
- Uncomfortable changes in stimulation (over and/or under stimulation).
- Temporary or persistent post-surgical pain at hardware implantation sites.
- CLS migration or suboptimal placement, which may result in pain or difficulty in charging.
- Seroma or hematoma at surgery sites.
- Epidural haemorrhage, spinal cord injury, possible paralysis or other neurological complications.
- Lead migration or suboptimal placement, which may result in undesirable stimulation changes.
- Breakage of the lead, or malfunction or failure of other system components, which may result in undesirable changes or loss of stimulation.
- Allergic response or tissue reaction to the implanted or external materials.
- Infection that may require hospitalisation with intravenous antibiotic therapy.
- Infection may result in epidural abscess that can lead to neurological harm.
- Cerebrospinal fluid (CSF) leakage with possible fistula formation.
- Gastrointestinal and/or genitourinary disruption or compromise.
- Inadequate pain relief following system implantation or over time.
- Erosion of the implanted components through the skin.
- Weakness, clumsiness, numbness, abnormal sensations or pain.
- Skin irritation.

The patient may require surgery (including revision, explant, and replacement) as a result of any of the above.

5 Percutaneous lead implant procedure

5.1 Overview

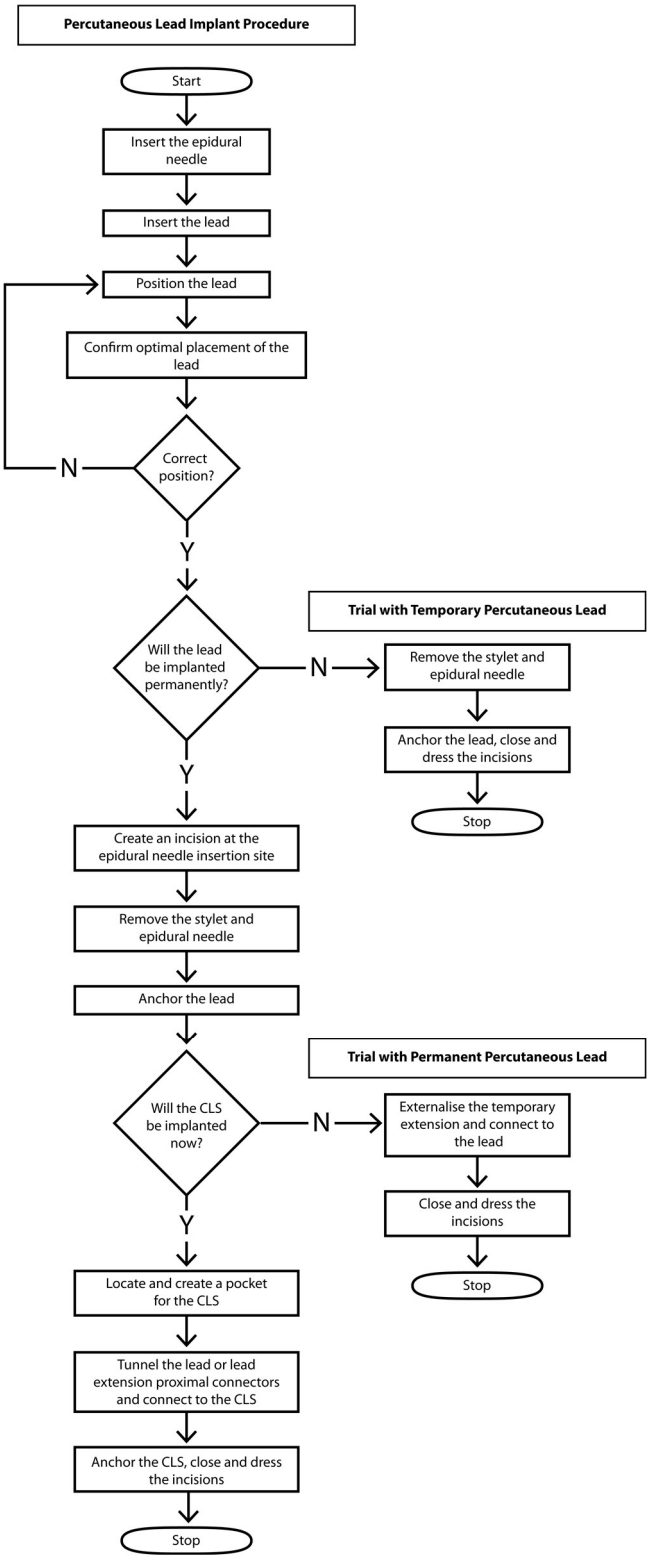


Figure 5.1: Overview of the percutaneous lead implantation process.

5.2 Percutaneous lead placement

5.2.1 Insert the epidural needle

1. Mark the patient's back using fluoroscopy for the required vertebral level.

   ⚠ **Warning:** The risk of patient injury increases as the needle insertion site moves up the spinal column from lumbar to cervical.

   Select an insertion site that provides the widest and easiest possible access to the epidural space to reduce the risk of patient injury due to spinal cord trauma.

   ⚠ **Caution:** It is recommended that the patient remain communicative during needle and lead placement to help mitigate any risk of neural injury.

2. Using an Epidural Needle from the surgical tools, insert the needle with the bevel up and a paramedian approach (refer to Figure 5.2) no greater than 45° angle to the skin into the epidural space (refer to Figure 5.3).

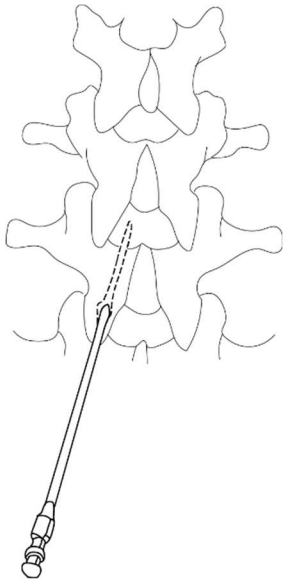


Figure 5.2: Inserting the needle with a paramedian approach.

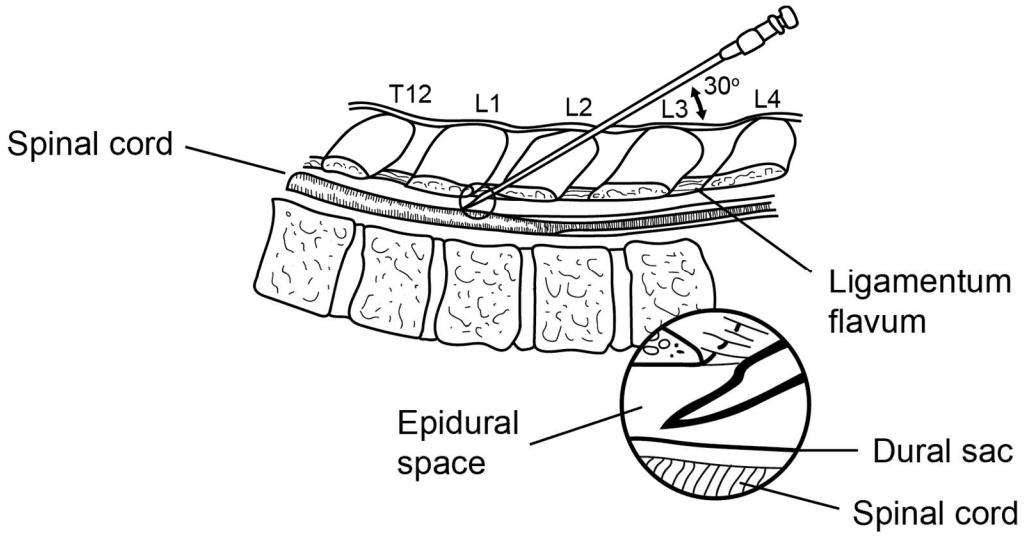


Figure 5.3: Insert the needle at no greater than 45°.

3. Confirm that you have entered the epidural space using a loss of resistance check.

5.2.2 Insert the percutaneous lead

1. Feed the percutaneous lead with the stylet, through the needle into the epidural space (refer to Figure 5.4).

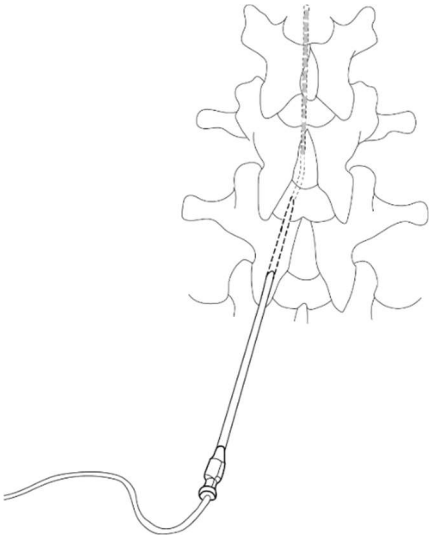


Figure 5.4: Feeding the percutaneous lead and stylet through the needle.

5.2.3 Position the percutaneous lead

1. Use the stylet handle to rotate and guide the percutaneous lead with one hand as you advance it with the other, while viewing it under fluoroscopy.
2. Continue advancing the percutaneous lead to the required location.
   - The percutaneous lead is pre-loaded with the bent stylet.

- You can replace the bent stylet with the straight stylet if required.

5.2.4 Confirm optimal placement of the lead

Physicians may have a preference on the method to confirm optimal lead placement in the operating room. Lead position may be confirmed anatomically using fluoroscopy, incorporating ECAP measurement, and/or through paresthesia mapping using intraoperative patient feedback.

Following lead placement based on required anatomical location, the surgeon connects the leads to the intraoperative cables inside the sterile field. The surgeon passes the end of the cables out of the sterile field to the programming clinician.

For intra-operative testing methods, refer to Section 10 'Intra-operative testing'. For intra-operative programming guidance, refer to the Evoke SCS System Clarity Clinical Manual accessible at http://www.saludamedical.com/manuals.

5.2.5 Create an incision at the epidural needle insertion site

Note: If the percutaneous lead will be externalized for a trial period, go to Section 7 'Trial with a temporary percutaneous lead', otherwise continue.

1. Create an incision around the needle sufficiently large to accommodate a strain relief loop if required (refer to Section 5.4) and the anchors for each percutaneous lead.

5.2.6 Remove the stylet and epidural needle

1. Carefully withdraw the epidural needle from the insertion site by sliding it along the percutaneous lead until clear of the body.
2. Carefully withdraw the stylet from the lead ensuring that the percutaneous lead position does not change.
3. Slide the epidural needle completely from the percutaneous lead.
4. Confirm lead position with fluoroscopy if required (and adjust position if needed).
5. Proceed to Section 5.3 'Anchor the lead'.

5.3 Anchor the lead

5.3.1 Position the anchor

1. Prepare the anchors for insertion by wetting with saline.
2. Slide the active anchor (refer to Figure 5.5A) or suture anchor (refer to Figure 5.5B) over the proximal connector end of the lead.
3. You may encounter some initial resistance as the proximal end has a stiffened section with a larger diameter. After feeding the lead into the anchor, grip the proximal connector end of the lead with your fingers and slide the anchor onto the lead.

⚠ **Caution:** Do not use surgical instruments to grip the proximal connectors

4. Slide the active or suture anchor along the lead until the distal portion of the anchor is at the lead entry site.

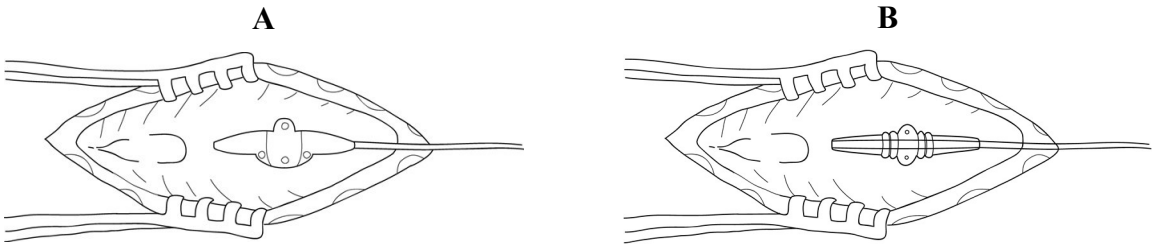


Figure 5.5: A) An active anchor positioned on a percutaneous lead.

B) A suture anchor positioned on a percutaneous lead.

5.3.2 Secure the anchor

1. Secure the anchor to the supraspinous ligament or deep fascia with 2 or 3 non-absorbable sutures looped through the suture holes on the anchor and/or in the grooves around the circumference of the anchor.

⚠ **Caution:** Do not use polypropylene sutures on the silicone anchor, as the polypropylene may damage or cause the anchor to fail.

5.3.2.1 Active anchor

1. Fit the head of the torque wrench (Figure 5.6A) supplied in the kit into the setscrew in the active anchor (refer to Figure 5.6B).

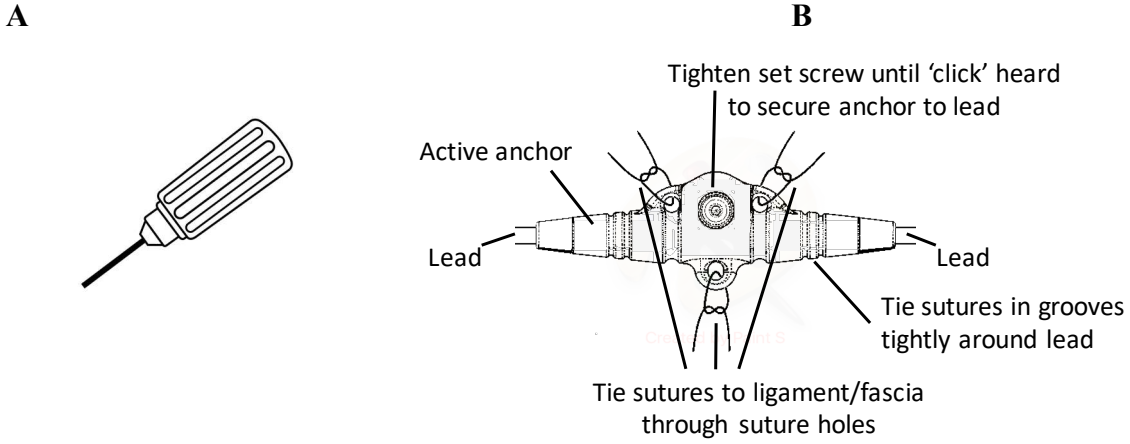


Figure 5.6: A) Torque wrench. B) Active anchor with screw secured against lead.

2. Use the torque wrench to gently tighten the setscrew clockwise until you hear a "click".

3. If needed, tie 1, 2, or 3 sutures in the grooves around the circumference of the anchor to secure the anchor to the lead (refer to Figure 5.6).

5.3.2.2 Suture anchor

1. Tie two sutures in the grooves around the circumference of the anchor.
2. Ensure the suture is tied tightly to minimize lead movement in the anchor (refer to Figure 5.7).

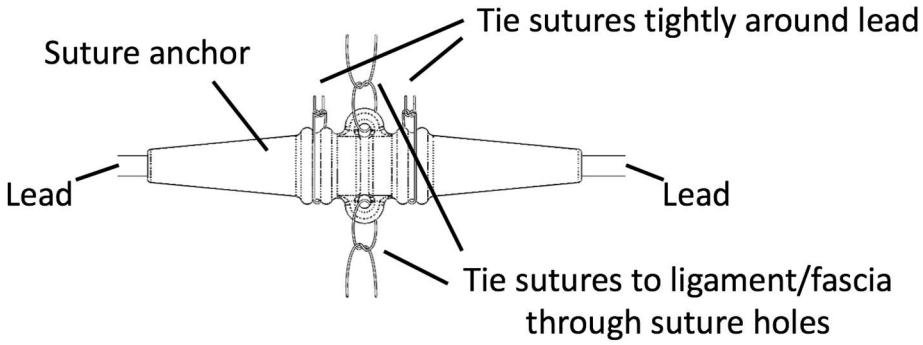


Figure 5.7: Securing the suture anchor.

5.4 Create a strain relief loop in the lead

1. A strain relief loop in the lead may be used to provide some slack and minimize tension on the lead due to body movement. If you consider the anchoring technique sufficient to minimize lead migration, the loop may not be required.
2. Using blunt dissection, create a small subcutaneous pocket at the incision site for a small loop of lead and lead extension connector blocks if used.
3. Create a loop in the lead and insert into the small pocket (refer to Figure 5.8).

   ⚠ **Caution:** In some patients, the loop may move or flip producing a lump under the skin and cause discomfort or problems at the anchor site wound, such as granuloma or infection.

   - If the CLS is to be implanted, proceed to Section 6 ‘Lead/Extension tunneling and CLS implant procedure’.
   - If a temporary extension will be externalized for a trial period proceed to Section 8 ‘Trial with a percutaneous extension’.

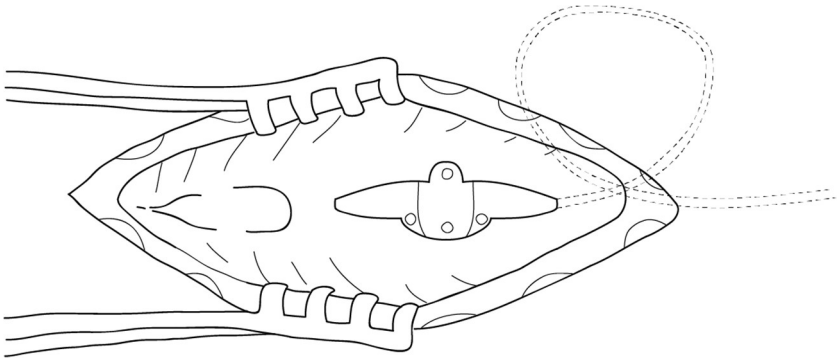


Figure 5.8: Small subcutaneous pocket for the strain relief loop and lead extension if used. Note that the strain relief loop should be on the CLS or lead extension side of the anchor.

6 Lead/Extension tunneling and CLS implant procedure

6.1 Locate and create a pocket for the CLS

Typically, the pocket is located in soft subcutaneous tissue at the top of the buttocks or on the patient's flank.

1. Mark the location for the incision and mark the size of the pocket required.
    - The pocket should be the same size as the CLS.
2. Create an incision with a scalpel and a subcutaneous pocket with blunt dissection.
    - The pocket should 0.5 cm to 2 cm (0.2 in to 0.8 in) below the skin surface.

⚠ **Caution:** Ensure that the CLS is not implanted too superficially, so that the risk of pain and skin erosion is minimized, or too deep so that charging is not compromised.

6.2 Tunnel the lead or lead extension

1. Create a pocket for the coiled leads and lead extension connector blocks if required (refer to Section 5.4).
    - For a single pass tunneling procedure (when the required tunnel is shorter than the tunneler) proceed to Section 6.2.1.
    - For an intermediate incision point tunneling procedure (when the required tunnel is longer than the tunneler) proceed to Section 6.2.2.

6.2.1 Using a single tunneling pass

Note: Two leads or lead extensions can be tunneled at the same time.

1. Create a pocket at the lead insertion site for the lead strain relief loop if required (refer to Section 5.4).

2. Insert the tunneler subcutaneously from the lead incision site to the CLS pocket.
3. Withdraw the tunneler, leaving the straw in the tunnel.
4. Slide the percutaneous lead or lead extension proximal connectors through the straw of the tunneler to the CLS pocket.
5. Gently slide the straw out of the tunnel, towards the CLS pocket, and off the end of the percutaneous lead or lead extension.
   - If using a lead extension proceed to Section 6.3.
   - If connecting the lead directly to the CLS proceed to Section 6.4.

   ⚠ **Caution:** Ensure that the leads or lead extensions are tunneled subcutaneously and are not too superficial, so that the risk of pain and skin erosion is minimized.

6.2.2 Using an intermediate incision point

Note: Two leads or lead extensions can be tunneled at the same time.

1. Create a pocket at the lead insertion site for the lead strain relief loop if required (refer to Section 5.4).
2. Create an intermediate incision between the lead incision site and the CLS pocket.
3. Insert the tunneler subcutaneously from the lead incision site to the intermediate incision site.
4. Withdraw the tunneler, leaving the straw in the tunnel.
5. Slide the lead or lead extension through the straw of the tunneler to the intermediate incision point.
6. Gently slide the straw out of the tunnel, towards the intermediate incision point, and off the end of the percutaneous lead or lead extension.
7. Re-attach the tunneler straw to the tunneler and tunnel subcutaneously from the intermediate incision site to the CLS pocket.
8. Withdraw the tunneler, leaving the straw in the tunnel.
9. Slide the lead or lead extension through the straw of the tunneler to the CLS pocket.
10. Gently slide the straw out of the tunnel, towards the CLS pocket, and off the end of the lead or lead extension.
    - If using a lead extension proceed to Section 6.3.
    - If connecting the lead directly to the CLS proceed to Section 6.4.

    ⚠ **Caution:** Ensure that the leads or lead extensions are tunneled subcutaneously and are not too superficial, so that the risk of pain and skin erosion is minimized.

6.3 Connect the lead extension to the lead

If a lead extension is not being use, proceed to Section 6.4.

1. Wipe down the lead proximal connectors prior to insertion into the lead extension to ensure that contacts are clean and dry.
2. Insert the lead proximal connectors into the lead extension connector block (refer to Figure 6.1).

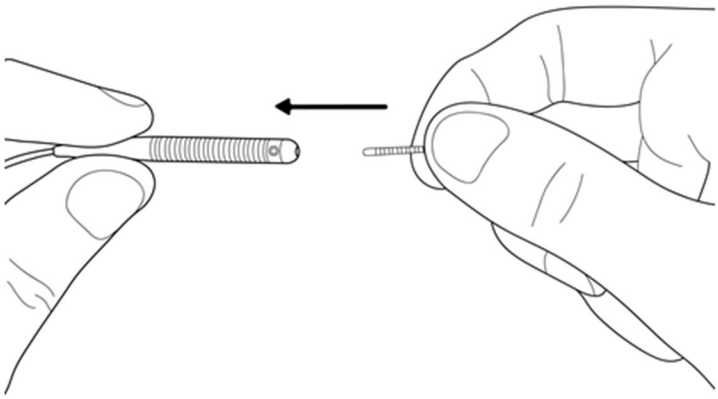


Figure 6.1: Inserting the lead proximal connectors into the lead extension connector block.

3. Gently slide the proximal connector until it hits a stop. All contacts should be within the connector block.

   Note: Take care to ensure that there is no bend or kink in the lead while inserting.

4. Confirm correct connection.
   - Connect lead extension to intraoperative cable to allow impedance measurement by an eCLS (refer to Section 10).
   - Alternatively, connect to CLS to allow impedance measurement (see Section 6.4).

   Note: Impedance measurement is to be completed by the programming clinician outside of the sterile field. The Evoke SCS System Clarity Clinical Manual provides specific information on this procedure. The programming clinician:

   a. Initiates wireless communication between the CI and the eCLS or CLS.

   b. Checks the impedance with the CI to ensure that any leads are connected properly to the lead extension and eCLS or CLS.

   c. It may be necessary to reinsert the leads if some electrodes are not connected properly to the lead extension and eCLS or CLS.

5. Fit the head of the torque wrench (supplied in the kit) into the setscrew in the lead extension connector block (refer to Figure 6.2).

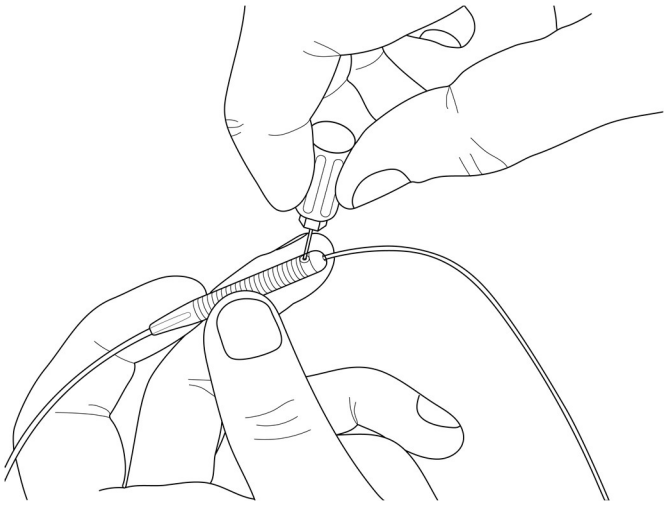


Figure 6.2: Tightening the set screw in the lead extension header block.

6. Gently tighten the setscrew clockwise until you hear a “click”.
7. Create a strain relief loop in the lead and place in the lead insertion site pocket if required (refer to Section 5.4).
8. Consider the final location of the lead extension connector block to facilitate access should it be required in the future.
9. Proceed to Section 6.4.

6.4 Connect to the CLS

2. Wipe down the lead or lead extension proximal connectors prior to insertion into the CLS to ensure that contacts are clean and dry.
3. Slide the proximal connector end of the lead or lead extension into its port in the header of the CLS (refer to Figure 6.3).
    a. Lead 1, electrodes 1-12, insert into the lower port.
    b. Lead 2, electrodes 13-24, insert into the upper port.

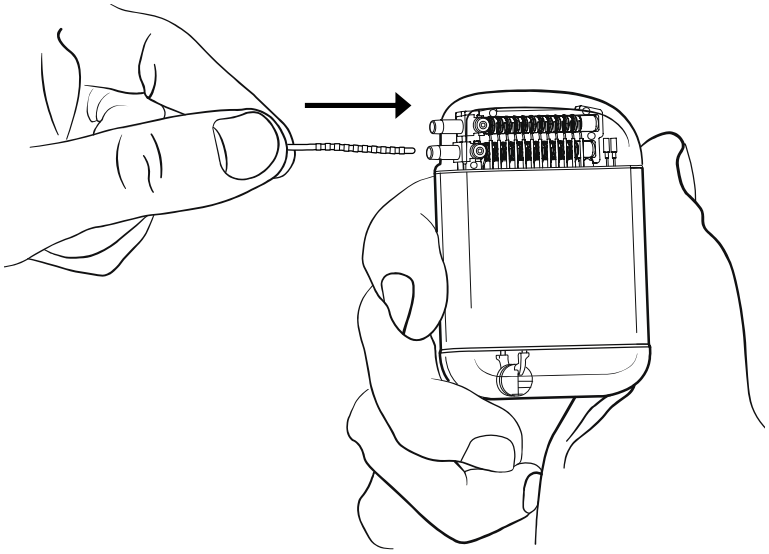


Figure 6.3: Inserting the proximal connectors into the CLS header.

4. Gently slide the proximal connector until it hits a stop.
    a. All contacts should be within the port.
    b. The end of the proximal connector should rest against the stop – visible through the header.

    Note: Take care to ensure that there is no bend or kink in the lead or lead extension while inserting.

5. Temporarily place the CLS partially within the CLS pocket.
6. Confirm correct connection.

    Note: This step is to be completed by the programming clinician outside of the sterile field. The Evoke SCS System Clarity Clinical Manual provides specific information on this procedure. The programming clinician:

    a. Initiates wireless communication between the CI and the CLS.
    b. Checks the impedance with the CI to ensure that any leads or lead extensions are connected properly to the CLS.
    c. It may be necessary to reinsert the leads or lead extensions if some electrodes are not connected properly to the CLS.

7. When satisfied that the leads or lead extensions are correctly inserted, use the torque wrench (supplied in the CLS kit) to tighten the setscrew on each port until you hear a “click” (refer to Figure 6.4).

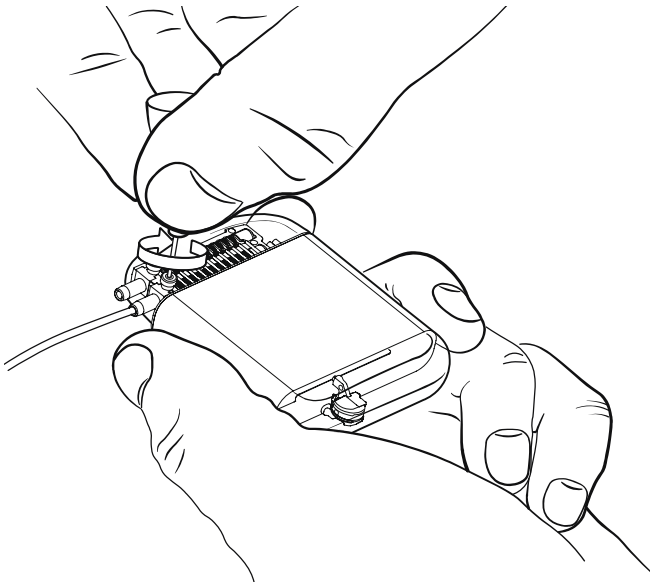


Figure 6.4: Tightening the port screws until you hear a "click".

8. If you are using only one lead, place the CLS port plug in the unused port to prevent moisture ingress (refer to Figure 6.5). Ensure that you push the port plug into the silicone strain relief.

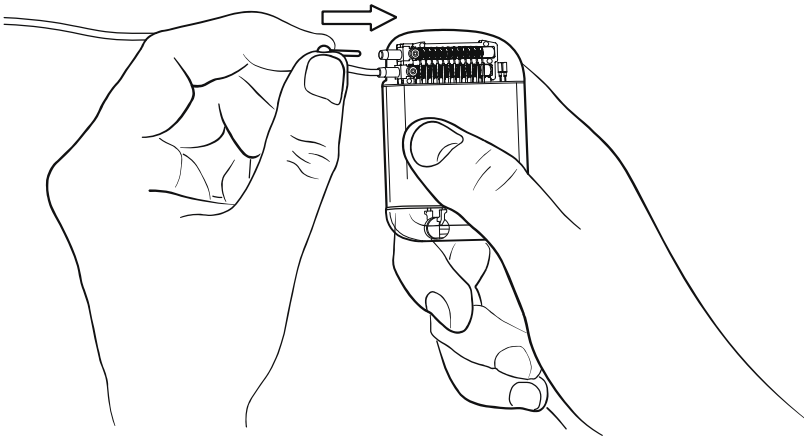


Figure 6.5: Inserting the port plug.

9. Tighten the setscrew with the torque wrench (supplied in the kit) until you hear a “click”.
10. Check that the port plug is secured and will not pop out after tightening the set screw.
11. Create a strain relief loop under the CLS (refer to Figure 6.6). If there is excess lead after this loop, coil the lead around the perimeter of the CLS or underneath.

    Note: The strain relief loop takes up any excess length and reduces tension in the lead during movement.

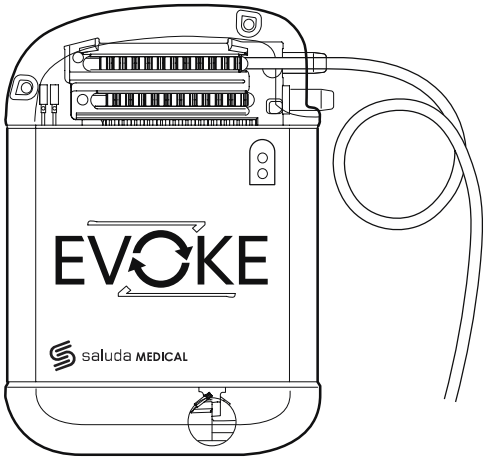


Figure 6.6: The lead exiting the CLS header with a strain relief loop.

⚠ **Caution:** Ensure that the lead is not bent at the port entry of the CLS header (refer to Figure 6.7).

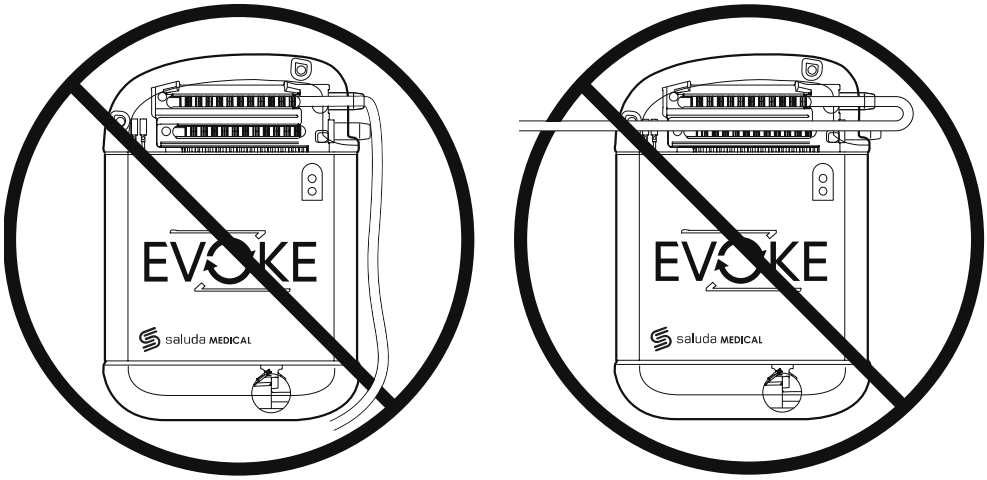


Figure 6.7: Examples where the lead has been bent at the port of entry of the CLS header. Take care to avoid this when creating the strain relief loop.

6.5 Anchor the CLS, close and dress the incisions

1. Insert the CLS into the pocket with the looped lead or lead extensions under the CLS.
2. Ensure that the writing on the CLS is facing up towards the skin so that charging will be possible.
3. Ensure that the CLS is between 0.5 cm to 2.0 cm (0.2 in and 0.8 in) under the skin so that charging will be possible.
4. Ensure that the CLS lays parallel to the skin surface so that charging is not compromised.

5. Secure the CLS to the subcutaneous fascia with sutures through the holes in the header of the CLS.
6. Close and dress the incisions taking care that the leads are not damaged in the closing process.

6.6 Post-operative procedures

For post-operative procedures and programming refer to the Evoke SCS System Clarity Clinical Manual.

7 Trial with a temporary percutaneous lead

Note: After completing steps 5.2.1 to 5.2.4 proceed to Section 7.1.

7.1 Remove the stylet and epidural needle

1. Carefully withdraw the epidural needle from the insertion site by sliding it along the percutaneous lead until clear of the body.
2. Carefully withdraw the stylet from the lead, ensuring that the percutaneous lead position does not change.
3. Slide the epidural needle completely from the percutaneous lead.
4. Confirm lead position with fluoroscopy if required.

7.2 Anchor the lead, close and dress the incisions

1. Using preferred techniques, close and dress the incision at the lead insertion site.
2. Using preferred method, ensure that the lead is firmly attached to the skin to minimize potential lead migration during the trial period.

   ⚠ **Caution:** Do not suture directly to the percutaneous lead as it may damage the lead or cause it to fail.

7.3 Post-operative procedures

For post-operative procedures and programming refer to the Evoke SCS System Clarity Clinical Manual.

7.4 Removing a percutaneous lead at the end of a trial

1. Disconnect the lead adapter from the eCLS.
2. Disconnect the lead adapter from the proximal connector of the lead.
3. If the lead has been secured to the skin this will need to be released.

4. Grasp the percutaneous lead between your thumb and forefinger, as close as possible to the patient's skin.
5. Gently withdraw the percutaneous lead from the epidural space.
6. If the patient is not proceeding straight to implantation surgery then clean the exit site, close and dress the incision.

8 Trial with a percutaneous extension

8.1 Externalize the temporary extension and connect to the lead

8.1.1 Create a subcutaneous pocket for the coiled lead and lead extension connector block

1. Create a subcutaneous pocket for the connector block of the lead extension.
2. Tunnel the lead to the pocket creating a strain relief loop at the lead insertion site if required (refer to Section 5.4).

8.1.2 Tunnel the lead extension

1. Select an exit point for the lead extension, ensuring it avoids the intended CLS pocket site.
2. Make an incision at the exit point.
3. Assemble the tunneler and passing straw.
4. Tunnel subcutaneously from the lead extension exit point to the pocket.
5. Withdraw the tunneler, leaving the straw in the tunnel.
6. Insert the proximal connector end of the lead extension into the passing straw at the pocket site.
7. Push the body of the lead extension through the passing straw until the proximal connectors have exited the passing straw.
8. Remove the passing straw towards the lead extension exit site.

⚠ **Caution:** Ensure that the leads or lead extensions are tunneled subcutaneously and are not too superficial, so that the risk of pain and skin erosion is minimized.

8.1.3 Connect the lead extension to the lead

1. Wipe down the lead proximal connectors prior to insertion into the lead extension to ensure that contacts are clean and dry.
2. Insert the lead proximal connectors into the lead extension connector block (refer to Figure 8.1).

Note: Take care to ensure that there is no bend or kink in the lead while inserting. Test impedance of the electrodes to confirm a good connection.

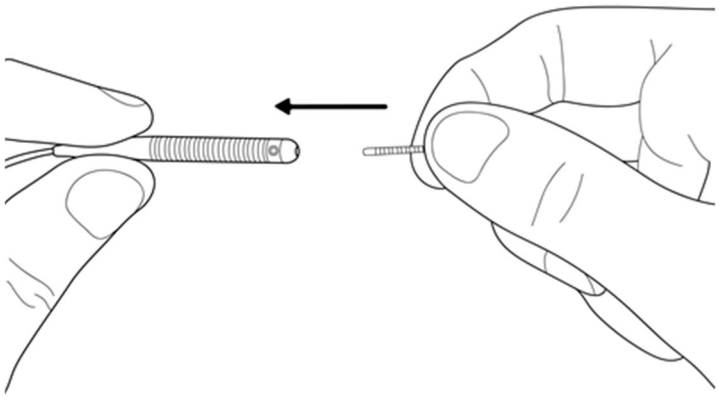


Figure 8.1: Inserting the lead proximal connectors into the lead extension connector block.

3. Gently slide the proximal connector until it hits a stop. All contacts should be within the connector block.
4. Confirm correct connection.
    - Connect lead extension to intraoperative cable to allow impedance measurement by an eCLS (refer to Section 10).

    Note: Impedance measurement is to be completed by the programming clinician outside of the sterile field. The Evoke SCS System Clarity Clinical Manual provides specific information on this procedure. The programming clinician:

    a. Initiates wireless communication between the CI and the eCLS.

    b. Checks the impedance with the CI to ensure that any leads are connected properly to the lead extension and eCLS.

    c. It may be necessary to reinsert the leads if some electrodes are not connected properly to the lead extension and eCLS.
5. Fit the head of the torque wrench (supplied in the kit) into the setscrew in the lead extension connector block (refer to Figure 8.2).
6. Gently tighten the setscrew clockwise until you hear a “click”.

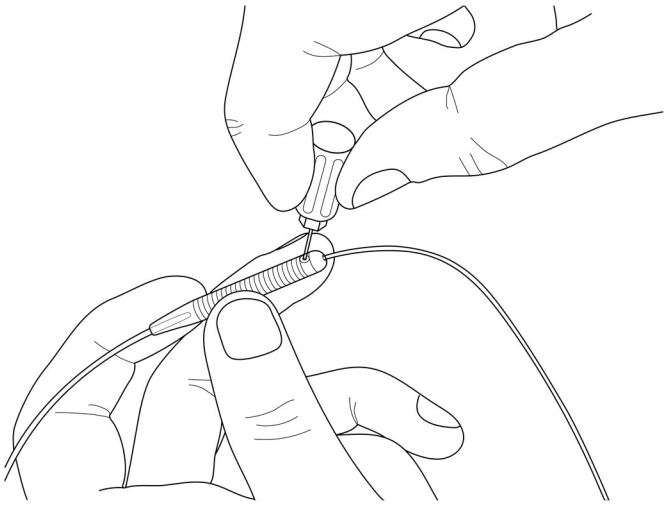


Figure 8.2: Tightening the set screw in the lead extension header block.

8.1.4 Place the lead, lead extension and connector block in the subcutaneous pocket

1. Coil the lead and subcutaneous section of the lead extension together with the connector block and carefully place in the pocket.
2. Place the connector block so it is easily accessible for later removal.

8.2 Close and dress the incisions

Using preferred techniques, close and dress the incision at the lead insertion site and the lead extension exit site.

⚠ **Caution:** Do not suture directly to the lead extension as it may damage the extension or cause it to fail.

8.3 Post-operative procedures

For post-operative procedures and programming refer to the Evoke SCS System Clarity Clinical Manual.

8.4 Removing a percutaneous extension at the end of a trial

1. Disconnect the lead adapter from the eCLS.
2. Disconnect the lead adapter from the proximal connector of the lead extension.
3. Remove external anchors or tape and clean the area around the lead extension exit site.
4. Gently pull the proximal end of the lead extension until 1-2cm is exposed from under the skin.
5. Using sterile scissors cut the newly exposed section of the lead extension and allow the

implanted part to retract under the skin.

6. If the implant procedure is to be scheduled for a later date, then close and dress the exit site. Otherwise, continue with the following steps or complete these steps at the implant procedure.
7. Prepare the lead implant site for surgery using preferred procedure.
8. Re-open the incision created when implanting the lead and carefully expose the coiled lead and lead extension.
9. Using the supplied torque wrench, loosen the setscrew in the lead extension connector block and withdraw the lead from the extension connector block.
10. Remove and discard the implanted section of the lead extension.
11. If proceeding to CLS and/or permanent lead extension implantation, refer to Section 6 'Lead/Extension tunneling and CLS implant procedure'.
12. If not proceeding to implant then remove and discard the anchors and leads (see Section 9 'Revision, replacement and explant surgery').

9 Revision, replacement and explant surgery

Surgery may be required in case of component failure, component movement, or site pain.

Note: Any component removed that is thought to be compromised should be returned to Saluda Medical for analysis via your Saluda Medical representative. All explanted CLS devices should be returned to Saluda Medical for proper disposal.

9.1 Open the component sites

1. Turn stimulation off using the patient's EPC or the Clinical Interface (CI).
2. Surgically open the lead and/or CLS pocket sites as required.

   Note: If the lead has been connected to the CLS via a lead extension, locate the lead extension connector block and surgically open the site.

   ⚠ **Warning:** Do not use electrosurgical techniques, such as electrocautery, over the leads or CLS, as this may cause tissue damage at the lead site and result in severe injury or cause damage to the CLS.

   ⚠ **Caution:** Take care with surgical instruments to ensure the leads and CLS are not damaged.
3. Cut any sutures and loosen setscrews with the torque wrench (supplied in the Spares kit) as required, to allow components to be moved.
4. Disconnect leads and CLS as required.

9.2 Percutaneous leads

1. If repositioning the lead:
    a. Insert a stylet (supplied in the Spares kit) into the lead.
    b. Guide the lead to the required position (refer to Section 5.2.3 to 5.2.4).

    Note: For intra-operative testing methods, refer to Section 10 'Intra-operative testing'.

    c. Anchor the lead (refer to Section 5.3 'Anchor the lead').
    d. Tunnel the lead then connect to the CLS (refer to Sections 6.2 to 6.5) or lead extension (Section 6.3).
2. If replacing the lead:
    a. Insert the epidural needle or a flexible cannula over the existing lead into the epidural space and withdraw the existing lead.

    Note: If it is difficult to insert the needle or cannula into the epidural space over the lead, a stylet may be inserted into the lead to stiffen it. Alternatively, the lead may be withdrawn, and the epidural needle inserted into a new location.

    b. Insert the new lead (refer to Sections 5.2.2 to 5.2.4).

    Note: For intra-operative testing methods, refer to Section 10 'Intra-operative testing'.

    c. Anchor the lead (refer to Section 5.3 'Anchor the lead').
    d. Tunnel the lead, then connect to the CLS or lead extension (refer to Sections 6.2 to 6.5).
3. If explanting and not replacing, the lead/s and anchors may be removed and returned to Saluda Medical for investigation or disposal. Close and dress the incisions.

9.3 CLS

1. For CLS replacement, remove the existing CLS and connect the new CLS to the percutaneous lead (refer to Sections 6.4 to 6.5).

⚠ **Caution:** The leads may be difficult to insert if replacing an existing CLS: Ref No. 3042 with a new CLS: Ref No. 3002. Use new leads or a new CLS: Ref No. 3042 instead.

2. To move the existing CLS to a new site, create a new pocket, tunnel the percutaneous leads to the new pocket, connect and anchor the CLS, then clean and dress the incisions (refer to Section 6).
3. If explanting and not replacing, the CLS may be removed and returned to Saluda Medical for investigation or disposal. Close and dress the incisions.

10 Intra-operative testing

The following should be completed after lead placement based on required anatomical location (see Section 5.2.4)

10.1 Using the eCLS

The eCLS connects to 2x leads via 2x intraoperative cables.

The intraoperative cable consists of a lead adapter attached to the cable to connect to the lead at the distal end and a plug to insert into the eCLS at the proximal end (see Figure 10.1).

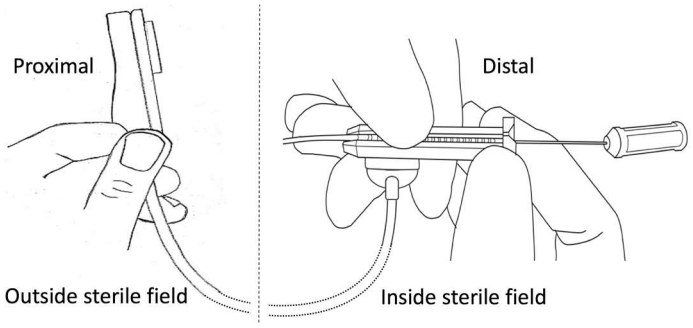


Figure 10.1: The intraoperative cable showing the proximal end after passing out of the sterile field and the distal end in the sterile field after inserting the lead proximal connector.

1. After connecting the lead to the distal end of the intraoperative cable (see Section 10.2), pass the proximal plug end of the cable out of the sterile field.
2. To connect a second lead and intraoperative cable repeat the above step.

   ⚠ **Caution:** The eCLS is not moisture resistant whilst the case is open. Take care that the eCLS does not come into contact with liquids whilst the case is open.

10.2 Connect the lead to the intraoperative cable

⚠ **Caution:** Avoid tension or pulling on the intraoperative cable whilst connected to avoid movement of the implanted leads.

1. Place the tip of the proximal connector end of the lead into the slot on the distal end of the intraoperative cable (see Figure 10.2). The stylet fits into the groove on the distal end.

   Note: It is not necessary to remove the lead Stylet.

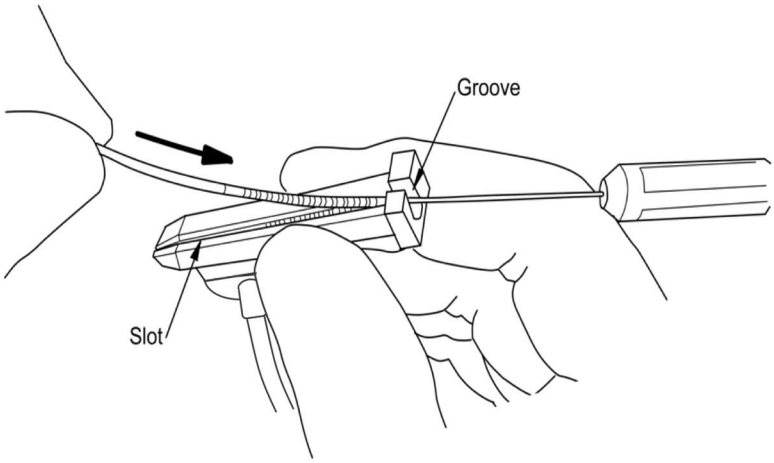


Figure 10.2: Placing tip of proximal connector into slot on the distal end of the intraoperative cable, with stylet fitting in groove.

2. Push the lead down into the slot completely using a finger (see Figure 10.3), so that the lead is flush with the top of the slot. The lead should not move when fully pushed into the slot. After the lead is in the slot, press down again along its length to ensure it is secure in the slot.

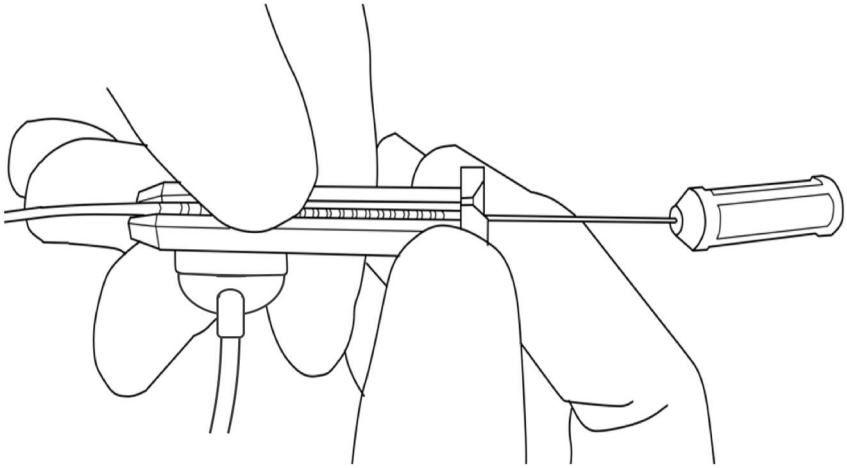


Figure 10.3: Pushing lead into slot.

3. Place the top cover of the distal end of the intraoperative cable over the lead, with the open side of the top cover aligned with the cable connection. Slide the top cover all the way onto the distal end until the notch on the top cover clips into place (see Figure 10.3).
4. To connect a second lead repeat the above steps.

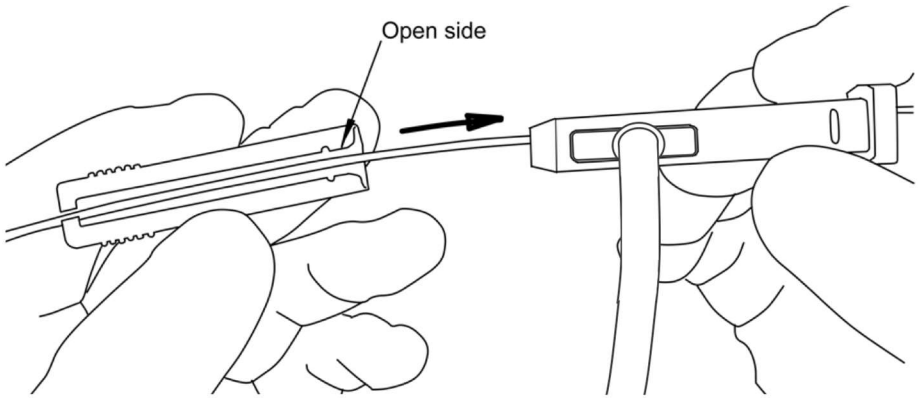


Figure 10.4: Placing the top cover over the lead and sliding onto distal end of the intraoperative cable until it clips into place.

10.3 Connect the intraoperative cable to the eCLS

This section is to be completed by the programming clinician outside of the sterile field.

⚠ **Caution:** Maintain a clear path between the patient and the eCLS whilst the intraoperative cable is connected to avoid tension or pulling on the implanted leads.

1. The programming clinician will plug the proximal end of the intraoperative cable into the port on the eCLS (refer to Figure 10.5).
2. To connect a second intraoperative cable, repeat the above step.

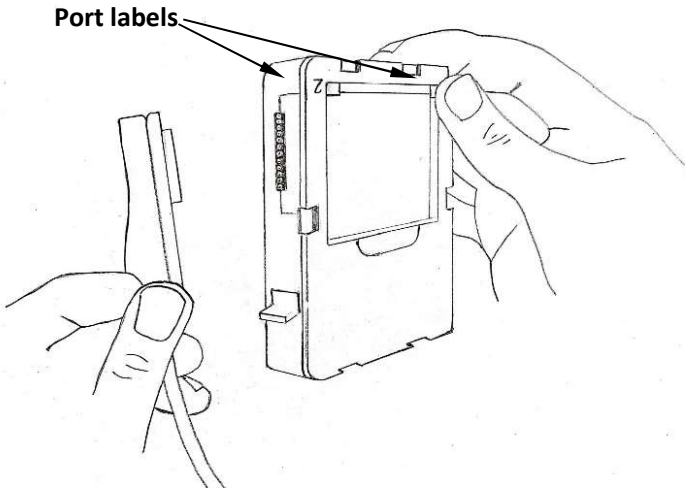


Figure 10.5: Connect the intraoperative cable to the eCLS. Port 2 (electrodes 13–24) is shown here. Port 1 (electrodes 1-12) is on the opposite side of the eCLS.

10.4 Confirm optimal lead placement

Confirmation of optimal lead placement may use one or more of the following methods to confirm medio-lateral lead location, dermatomal coverage, ability to measure ECAPs, and/or paresthesia coverage of the pain areas:

- ECAP measurement - go to Section 10.4.1.
- Paresthesia mapping - go to Section 10.4.2.

10.4.1 ECAP measurement

Refer to the Evoke SCS System Clarity Clinical Manual for detailed programming instructions.

1. Connect the CI to the eCLS.
2. Check electrode impedance using the CI to ensure the leads are connected properly.
   - If electrode impedance is greater than 4000 Ω check all the connections.
   - Check impedance after each reconnection of the proximal connector to the intraoperative cable.
3. Select the stimulation and measurement electrodes and settings.
4. Verify that an ECAP can be measured by stimulating, for example, at the top and bottom of the lead.
   - If the ECAP measured is not satisfactory, change the electrodes, stimulation or measurement settings using the CI or move the percutaneous lead to a new position.
   - Verify ECAP measurement after changing settings or moving the percutaneous lead.
5. When satisfied with the lead placement, disconnect the intraoperative cable from the lead.

10.4.2 Paresthesia mapping

Refer to the Evoke SCS System Clarity Clinical Manual for detailed programming instructions.

1. Connect the CI to the eCLS.
2. Check electrode impedance using the CI to ensure the leads are connected properly.
   - If electrode impedance is greater than 4000 Ω check all the connections.
   - Check impedance after each reconnection of the proximal connector to the adapter.
3. Select the stimulation and measurement electrodes and settings.
4. Increase stimulation current until the patient reports a medium level of paresthesia (tingling).
   - Adjust settings to ensure that ECAPs are being measured correctly.
5. The patient should report paresthesia coverage of the body that aligns with their pain area.
   - If paresthesia coverage is not satisfactory, change the electrode and stimulation settings using the CI or move the percutaneous lead to a new position.

- If moving the percutaneous lead with stimulation on, enable closed-loop to automatically adjust current.
- Retest paresthesia coverage after changing settings or moving the percutaneous lead.

6. When satisfied with the lead placement, disconnect the intraoperative cable from the lead.

   Note: If the lead or lead extension will be externalized for an extended trial period, go to Section 7 'Trial with a temporary percutaneous lead' or Section 8 'Trial with a percutaneous extension', otherwise go to Section 6 'Lead/Extension tunneling and CLS implant procedure'.

10.5 Repositioning the lead

If a lead needs to be moved the intraoperative cable may remain connected to the lead.

1. For lead steering, hold the intraoperative cable and turn the stylet handle between thumb and index finger (see Figure 10.6).
2. When the lead is in the desired location, confirm optimal lead placement (see Section 10.4).

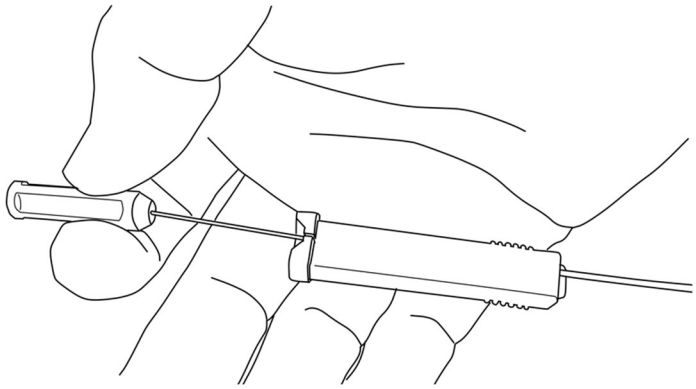


Figure 10.6: Lead steering with the intraoperative cable connected to the lead.

10.6 Disconnect the lead from the intraoperative cable

1. When satisfied with the lead placement you may disconnect the distal end of the intraoperative cable from the lead.
2. Hold the top cover between thumb and index finger of one hand and the distal end with the other hand
3. Slide the top cover off the distal end
4. Lift the lead gently out of the slot.

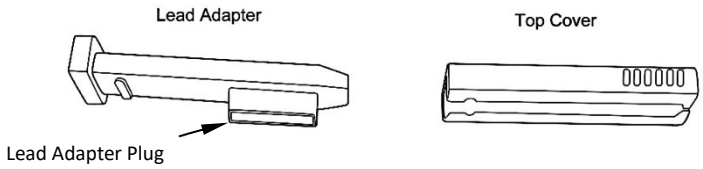
11 Preparing the eCLS for the trial stimulation period

If the patient has externalized leads or lead extensions for the purpose of a temporary trial, the externalized leads or extensions will need to be connected to the lead adapter (see Section 11.1), which in turn will need to be connected to the eCLS (see Section 11.2). The eCLS with a fully charged battery (see Section 11.4) is then placed into the eCLS case (see Section 11.3) and secured for the trial stimulation period (see Section 11.5).

11.1 Connect the lead or lead extension to the lead adapter

5. Place the tip of the proximal connector end of the lead into the end of the lead adapter slot (Figure 11.1).

A)



B)

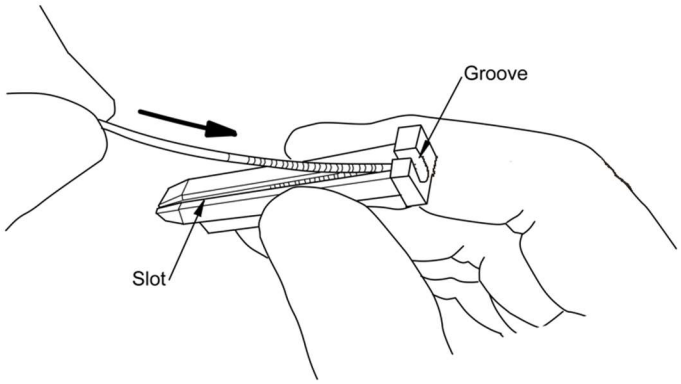


Figure 11.1: A) The lead adapter. B) Placing the tip of the proximal connector into the lead adapter slot.

6. Push the lead down into the slot completely using your finger (Figure 11.2), so that the lead is flush with the top of the slot. The lead should not move when fully pushed into the slot. After the lead is in the slot, press down again along its length to ensure it is secure in the slot.

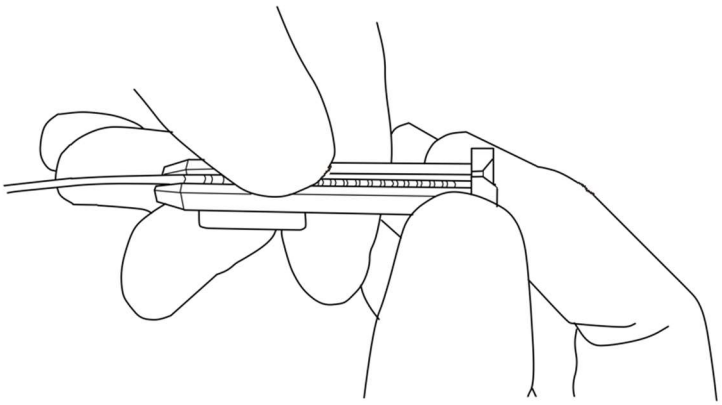


Figure 11.2: Pushing lead into lead adapter slot.

7. Place the top cover of the lead adapter over the lead, with the open side of the top cover aligned with the lead adapter plug. Slide the top cover all the way onto the lead adapter until the notch on the top cover clips into place (refer to Figure 11.3).

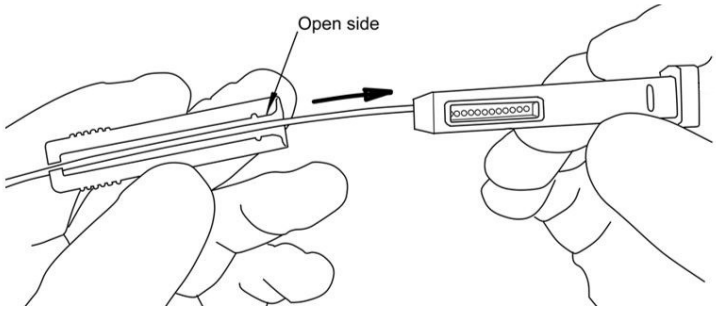


Figure 11.3: Placing the top cover over the lead and sliding onto lead adapter until it clips into place.

11.2 Connect the lead adapter to the eCLS

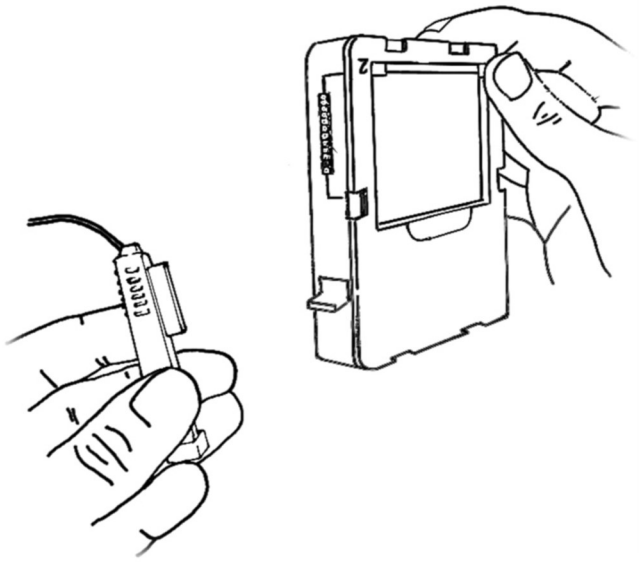


Figure 11.4: Connecting the lead adapter to the eCLS. Port 2 (electrodes 13–24) is shown here. Port 1 (electrodes 1-12) is on the opposite side of the eCLS.

1. Line up the end of the lead adapter plug with the socket on the eCLS port to ensure the connector pins do not get bent (Figure 11.4). Push the lead adapter plug into the eCLS until it clips into place.
    a. The eCLS ports are labelled ‘1’ on one side for electrodes 1-12 and ‘2’ on the other side for electrodes 13-24.

    Note: If you are reconnecting leads to an eCLS that has already been programmed, ensure that the lead and lead adapter are reinserted into the same ports as used during previous programming sessions.
2. To connect a second lead to the lead adapter, repeat the steps in Sections 11 and 11.2.

11.3 Place the eCLS into the case

1. Ensure that a fully charged battery is inserted in the eCLS (see Section 11.4; Figure 11.5).
2. Open the eCLS case with the lead exits pointing up. Place the eCLS into the orange seal side of the case, with the eCLS battery facing up and the leads pointing up over the lead exits (see Figure 11.5).
3. Place the leads into the slots in the seal at the lead exits.

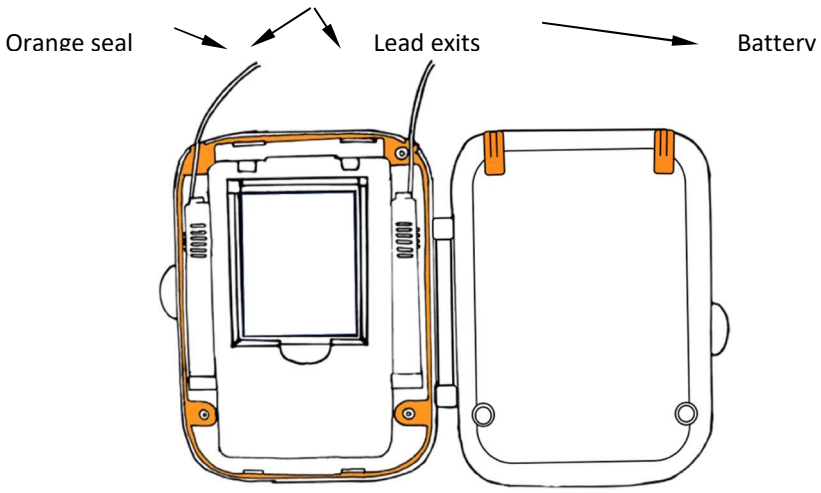


Figure 11.5: Place the eCLS with leads connected into the eCLS Case.

4. Close the eCLS case by folding the case shut until it snaps closed (Figure 11.6). Ensure that the leads do not move from the slots in the seal. The leads may be damaged when the case is closed if they are not in the slots in the seal at the lead exits.

Figure 11.6: eCLS with two leads connected enclosed in case.

5. After the eCLS is connected and in the eCLS case it may be programmed (refer to Evoke SCS System Clarity Clinical Manual) and set up for the patient to wear for the trial stimulation period (see Section 11.5).

11.4 Charge the eCLS battery

1. Before the patient goes home with an eCLS, a fully charged eCLS battery should be in place (see Figure 11.5).
2. Check the battery voltage with the CPA (refer to Evoke SCS System Clarity Clinical Manual).
3. To charge the eCLS battery:

   a. Disconnect the intraoperative cables or lead adapters from the eCLS.
   b. Remove the battery from the eCLS.
   c. Charge the battery using the supplied eCLS battery charger.
4. Place the charged battery into the eCLS
5. Connect intraoperative cables or lead adapters to the eCLS.

11.5 Secure the eCLS for the trial stimulation period

1. The eCLS may be worn by the patient for the duration of the trial stimulation period in either of two ways:
   a. In a pouch (see the Accessory Belt section in the Evoke SCS System User Manual), or
   b. Placed on a dressing and taped to the skin by the clinician.
2. The eCLS and leads remain connected inside the eCLS case during the trial stimulation period. If the leads become disconnected from the eCLS or the patient needs to disconnect the eCLS for any reason the patient should return to the clinic.

12 Sterilization

All items detailed in this document, with the exception of the eCLS, EPC, Charger and Accessory Belt, are provided sterile and are for single use only. None of these items should be re-sterilized or reused. Sterilization method is Ethylene Oxide.

DO NOT STERILIZE the eCLS, EPC or Charger. These devices are external system components that do not require sterilization. Clean these components regularly as detailed in Section 15 ‘Maintenance of the Evoke eCLS, EPC, and Charger’.

13 Patient ID card

Every CLS is supplied with a Patient ID Card for the clinician to complete.

- Give the completed Patient ID Card to the patient so that they can use it to show other medical practitioners or security personnel that they have an active implanted medical device.
- The Evoke System has not been tested for MRI compatibility and is MR unsafe. The Patient ID Card indicates that the patient **must not** undergo an MRI scan with the Evoke System implanted.

14 Identifying the Evoke CLS

Prior to implantation, the serial number of the CLS can be located on the surface of the CLS. Following implantation, the serial number of the CLS can be found on the patient's ID Card, or can be identified using the Clinical Programming Application, in communication with the CLS.

The CLS can also be identified by a radiopaque marker, which can be viewed by standard x-ray procedures. The radiopaque characters consist of a code in the following format: SME DYY, where SME indicates Saluda Medical, D indicates the CLS model, and YY indicates the two-digit year of manufacture.

15 Maintenance of the Evoke eCLS, EPC, and Charger

The eCLS, EPC, and Charger are designed to be used by multiple patients during a temporary trial stimulation period, and so should be cleaned thoroughly between patients. The devices can be cleaned with a soft cloth dampened with a mild disinfectant or alcohol.

⚠ **Caution:** The battery must be removed from the eCLS prior to cleaning.

Do not use abrasive cleaners and avoid wiping the connectors on the Charger and eCLS, if applicable.

DO NOT STERILIZE the eCLS, EPC or Charger. These items are supplied non-sterile. Sterilization could damage these components beyond repair and impact their ability to perform as intended.

The eCLS is supplied with a replaceable, rechargeable battery with a dedicated battery charger. Please refer to Section 11.4 for instructions on eCLS battery recharging.

16 Package contents

Table 16.1: Package contents.

Package	***Package Contents***
Evoke Closed-Loop Stimulator **(Ref No.: 3042)**	1 x Evoke Closed-Loop Stimulator 1 x Evoke CLS Port Plug 1 x Torque Wrench
Evoke External Closed-Loop Stimulator **(Ref No.: 3036)**	1 x Evoke External Closed-Loop Stimulator
Evoke eCLS Case **(Ref No.: 3035)**	1 x Evoke eCLS Case 2 x Lead Adapters 2 x Top Covers

Package	*Package Contents*
Evoke CAP12 Percutaneous Lead Kit - 60 cm (Ref No.: 3008) **Evoke CAP12 Percutaneous Lead Kit - 90 cm (Ref No.: 3009)** **Evoke CAP12 Trial Lead Kit - 60 cm (Ref No.: 3016)** **Evoke CAP12 Trial Lead Kit - 90 cm (Ref No.: 3017)**	1 x Evoke CAP12 Percutaneous, (preloaded with Bent Stylet of 0.36 mm (0.014 in) diameter). 1 x Evoke Suture Anchor 1 x Epidural Needle, 14-gauge, 11.3 cm (4.5 in) spoonbill type. 1 x Straight Stylet of 0.36 mm (0.014 in) diameter.
Evoke CAP12X Lead Extension Kit – 55 cm (Ref No.: 3011)	1 x Evoke CAP12X Lead Extension 1 x Torque Wrench
Evoke Active Anchor Kit (Ref No.: 3043)	2 x Evoke Active Anchor 1 x Torque Wrench
Evoke Tunneler (Ref No.: 3012)	1 x Tunneler (with passing straw and tip protector).
Evoke Intraoperative Cable Kit (Ref No.: 3034)	1 x Intraoperative Cable 1 x Top Cover
Epidural Needle, 6.5” (Ref No.: 3014)	1 x Epidural Needle, 14-gauge, 16.5 cm (6.5 in) spoonbill type.
Evoke Spares Kit (Ref No.: 3015)	2 x Evoke Suture Anchors 1 x Epidural Needle, 14-gauge, 11.3 cm (4.5 in) spoonbill type. 1 x Bent Stylet (15° angle) of 0.36 mm (0.014 in) diameter, compatible with 90 cm Percutaneous Lead. 1 x Straight Stylet of 0.36 mm (0.014 in) diameter, compatible with 90 cm Percutaneous Lead. 1 x Bent Stylet (15° angle) of 0.36 mm (0.014 in) diameter, compatible with 60 cm Percutaneous Lead. 1 x Straight Stylet of 0.36 mm (0.014 in) diameter, compatible with 60 cm Percutaneous Lead. 1 x Torque Wrench 1 x Evoke CLS Port Plug

Package	*Package Contents*
Evoke Accessory Belt (Ref No.: 3039)	1 x Evoke Accessory Belt

17 Technical Specifications

17.1 Evoke SCS System Components

Table 17.1: Evoke SCS System Components.

Ref Number	*Product Description*
3042	Evoke Closed-Loop Stimulator (CLS)
3040	Evoke Patient Controller
3004	Evoke Clinical System Transceiver (CST)
3006	Evoke Charger (US)
3008	Evoke CAP12 Percutaneous Lead Kit - 60cm
3009	Evoke CAP12 Percutaneous Lead Kit - 90cm
3011	Evoke CAP12X Lead Extension Kit - 55cm
3043	Evoke Active Anchor Kit
3012	Evoke Tunneler
3014	Evoke Epidural Needle, 6.5"
3015	Evoke Spares Kit
3016	Evoke CAP12 Trial Lead Kit - 60cm
3017	Evoke CAP12 Trial Lead Kit - 90cm
3036	Evoke External Closed-Loop Stimulator (eCLS)
3035	Evoke eCLS Case
3024	Clinical Interface (CI)

Ref Number	*Product Description*
3034	Evoke Intraoperative Cable Kit
3039	Evoke Accessory Belt Kit

17.2 Device Specifications

Refer to the Evoke SCS System Clarity Clinical Manual and Evoke SCS System User Manual for device specifications for additional components of the Evoke SCS System.

17.2.1 Evoke CLS

Table 17.2: Evoke CLS.

Materials	Case	Titanium
	Header	Epoxy
	Seals	Liquid silicone rubber
	Connector springs	Platinum Iridium (24 x connectors)
	Set screw	Stainless steel
Dimensions	68 mm x 48 mm x 12 mm (2.7 in x 1.9 in x 0.47 in)	
Volume	33 cm^3 (2 in^3)	
Weight	50 g (1.76 oz.)	
Lead ports	2	Each lead or lead extension is secured by a set screw at the port entry
Electrodes	25	Port 1: electrodes 1-12 Port 2: electrodes 13-24 CLS case is electrode 25 (recording only)
Stimulation parameters	Current	0 mA – 50mA (20 mA @750 Ω)
	Pulse Width	20 µs – 1000 µs
	Frequency	10 Hz – 1500 Hz

Radio frequency communication	MICS band	402 - 405 MHz
	8 channels*	Centre frequency (MHz): 402.45, 402.75, 403.05, 403.35, 403.65, 403.95, 404.25, 404.55
	Transmit/Receive Channel Bandwidth	300 kHz
	Modulation type	Frequency Shift Keying (FSK)
	Range	1.0 m (3.3 ft.)
	Effective Isotropic Radiated Power (EIRP)	25 µW (-16.02 dBm) maximum
	FCC ID	2AYGR-3042
*Channels are automatically selected when the communication session begins.		
Battery	200 mAh Li-Ion rechargeable battery	
Battery life	Greater than 10 years* at moderate settings (current = 5.0 mA, pulse width = 200 µs, frequency = 60 Hz, impedance = 750 Ω, 24hrs/day usage)	
	Greater than 10 years* for more than 95% of patients	
*End of CLS Battery Life is defined by Saluda Medical as the point at which the device can no longer maintain enough charge to provide 24hrs of therapy. At higher or lower settings this defined end of life could be shorter or longer respectively		
Charging	Transcutaneous charging using inductive coupling with an external coil	
	Implant depth	5 mm to 20 mm (0.2 in to 0.8 in)
Recording amplifier gain	Low: 250x High: 1000x	
Data recording	32 MB, up to 1 year (Stimulation usage, ECAP amplitude and current statistics)	
Radio opaque identifier	"SME BYY" Where "SME" is Saluda Medical, "B" is the CLS model and YY is the two-digit year of manufacture	
Storage & Transportation Conditions	Temperature:	Min: -10 °C (14 °F) Max: 55 °C (131 °F)
Operating Conditions	Pressure:	70 kPa (0.69 atm) Max: 150 kPa (1.48 atm)

17.2.2 Evoke eCLS (includes Case and Lead Adapters)

Table 17-3: Evoke eCLS.

Materials	eCLS body and case	ABS Plastic	
	Case Seal	TPE	
Dimensions	100 mm x 85 mm x 20 mm (3.9 in x 3.4 in x 0.8 in)		
Weight	96 g (3.4 oz.)		
Electrodes	24	Port 1: electrodes 1-12, Port 2: electrodes 13-24	
Functional specifications	All other functional specifications are the same as the CLS (See Section 17.2)		
Radio frequency communication	MICS band	402 - 405 MHz	
	8 channels*	Centre frequency (MHz): 402.45, 402.75, 403.05, 403.35, 403.65, 403.95, 404.25, 404.55	
	Transmit/Receive Channel Bandwidth	300 kHz	
	Modulation type	Frequency Shift Keying (FSK)	
	Range	1.0 m (3.3 ft.)	
	Effective Isotropic Radiated Power (EIRP)	25 µW (-16.02 dBm) maximum	
	FCC ID	2AYGR-3036	
*Channels are automatically selected when the communication session begins.			
Battery	800 mAh Li-ion rechargeable battery		
Battery Life	Greater than 14 days between charges at moderate settings.		
	Greater than 7 days between charges for more than 95% of patients.		
Charging	Li-Ion battery charger		
Ingress Protection eCLS in case	IP22 Rating for protection against access of solid objects greater than or equal to 12.5mm, and for vertically dripping water when the device is tilted 15 degrees.		
eCLS	IP30 Rating for protection against solid objects greater than or equal to 2.5mm, and no protection against water.		
IEC 60601-1 / EN 60601-1 Classification	Type BF Applied Part		
	Internally Powered Medical Electrical Equipment		
	Continuous Operation		
Storage & Transportation Conditions	Temperature:	Min: -10 °C (14 °F)	Max: 55 °C (131 °F)
	Humidity:	Min: 0% RH	Max: 90% RH
	Pressure:	70kPa (0.69 atm)	Max: 106kPa (1.05 atm)

Operating Conditions	Temperature:	Min: 5 °C (41 °F)	Max: 40 °C (104 °F)
	Humidity:	Min: 15% RH	Max: 90% RH
	Pressure:	70 kPa (0.69 atm)	Max: 106 kPa (1.05 atm)

Table 17-4: Lead Adapter.

Materials	Body	ABS Plastic
Dimensions	55 x 13 x 13 mm (2.2 x 0.5 x 0.5 in)	
Lead connection	Ports	1
	12 spring connectors	Au plating on stainless steel
Lead Adapter to eCLS connection	12 pin plug	

17.2.3 Evoke CAP12 Percutaneous Lead (includes Trial Leads)

Table 17.5: Evoke CAP12 Percutaneous Lead (includes Trial Leads).

Materials	Lead body	Pellethane	
	Lead ends	Pellethane	
	Distal electrodes	Platinum Iridium	
	Proximal connectors	Platinum Iridium	
	Retention ring	MP35N[1]	
	Conductors	35N LT with Ag core (19 strand cable)	
Dimensions	Lengths	60 cm (1.97 ft.) or 90 cm (2.95 ft.)	
	Diameter	1.32 mm (0.05 in)	
Electrodes	Number	12	
	Length	3 mm (0.12 in)	
	Pitch	7 mm (0.276 in)	
Connectors	Length	1.02 mm (0.040 in)	
	Pitch	1.96 mm (0.077 in) center to center	
Storage & Transportation Conditions	Temperature:	Min: -10 °C (14 °F)	Max: 55 °C (131 °F)
Operating Conditions	Pressure:	70 kPa (0.69 atm)	Max: 150 kPa (1.48 atm)
	[1] Alloy of Nickel, Cobalt, Chromium and Molybdenum. MP35N is not in contact with tissue, but may be in contact with body fluid.		

17.2.4 Evoke CAP12X Lead Extension

Table 17.6: Evoke Lead Extension.

Materials	Lead extension body	Pellethane	
	Lead extension ends	Pellethane	
	Proximal connectors	Platinum Iridium	
	Retention ring	MP35N[1]	
	Connector springs	Platinum Iridium	
	Set screw	Titanium	
	Header body	Silicone	
Dimensions	Length	55 cm (1.8 ft.)	
	Body Diameter	1.32 mm (0.05 in)	
	Header Length	41 mm (1.62 in)	
	Header Diameter	5.23 mm (0.21 in)	
Connectors	Number	12	
	Length	1.02 mm (0.040 in)	
	Pitch	1.96 mm (0.077 in) center to center	
Storage & Transportation Conditions	Temperature:	Min: -10 °C (14 °F)	Max: 55 °C (131 °F)
Operating Conditions	Pressure:	70 kPa (0.69 atm)	Max: 150 kPa (1.48 atm)
	[1] Alloy of Nickel, Cobalt, Chromium and Molybdenum. MP35N is not in contact with tissue, but may be in contact with body fluid.		

17.2.5 Surgical accessories

Table 17.7 below lists the specifications for the surgical accessories found in the various component kits as detailed in Section 16 'Package contents'.

Transport and store surgical accessories at temperatures from -10 °C (14 °F) to 55 °C (131 °F). Operate surgical accessories at pressures from 70kPa (0.69 atm) to 150kPa (1.48kPa).

Table 17.7: Surgical Accessories.

Epidural Needle	**Material**	Stylet and Cannula	Stainless Steel
		Hub and Cap	Nickel-plated Brass
	Dimensions	Lengths	113 mm (4.5 in) and 165 mm (6.5 in)
		Diameter	14 gauge (1.74 mm internal)
Stylet	**Forms**	Straight or bent (15° angle)	
	Material	Body	Stainless steel
		Stylet hub	ABS Plastic
	Dimensions	Length	To suit each electrode length
		Diameter	0.356 mm (0.014 in)
Suture Anchor	**Form**	Two suture eyelets	
	Material	Silicone rubber	
	Diameter	5 mm (0.20 in)	
	Length	35 mm (1.38 in)	
Active Anchor	**Form**	Three suture eyelets, and a set screw to secure the lead	
	Materials	Body	Silicone rubber
		Set screw	Titanium
		Set Screw Block	Titanium
	Diameter	5.4 mm (0.21 in)	
	Length	35 mm (1.38 in)	
Tunneler	**Materials**	Body	Stainless steel
		Straw	PTFE
	Dimensions	Length	279.4 mm (11 in)
		Straw length	203.2 mm (8 in)
		Body diameter	4 mm (0.157 in)
		Straw ID	4.22 mm (0.166 in)
		Straw OD	4.60 mm (0.181 in)

Torque Wrench	**Materials**	Handle	Polyetherimide plastic
		Shaft	Stainless steel
	Dimensions	Length	43 mm (1.69 in)
		Bit size	1 mm (0.04 in) hex key
	Torque	0.042 Nm (6 oz-in)	
CLS Port Plug	**Materials**	Stainless steel	
	Length	13 mm (0.51 in)	
Intra-operative Cable	**Materials**	Socket	ABS Plastic
		Plug	ABS Plastic
		Cable	TPE
	Dimensions	Socket	55 x 13 x 13 mm (2.2 x 0.5 x 0.5 in)
		Plug	62.5 x 19.8 x 14.5 mm (2.5 x 0.8 x 0.6 in)
	Cable Length	2.5m (8 ft. 2.4 in)	
	Lead Connection	Ports	1
		12 spring connectors	Au plating on stainless steel
	eCLS Connection	12 pin plug	

17.3 Wireless Communication

17.3.1 Quality of Service & Wireless Coexistence

The Evoke SCS System employs a wireless communication link operating in the 402-405 MHz MICS frequency band. This band is designated for implantable medical devices and enables communication between the CLS/eCLS and the CST or EPC.

At the beginning of each communication session, the CST or EPC automatically scans 8 channels in the frequency band and selects the least congested channel for communication. All communication is error-checked. The user is notified if the wireless communication link fails to connect.

The communication range between the CST/EPC and the CLS/eCLS is typically 3.3 feet (1 meter). If you experience issues with the wireless communication between the CST/EPC and CLS/eCLS, try the following:

- Decrease the distance between the devices.
- Move the devices away from other devices that may be causing interference (see Section 17.4).
- Restart the CPA, wait a few minutes and try connecting again.
- Do not operate other wireless devices, such as a mobile phone, tablet or laptop, at the same time.

17.3.2 Wireless Security

The Evoke SCS System has a communication range of 3.3 feet (1 meter). To enable the CST/EPC to communicate with an eCLS or CLS, it must first be paired with that stimulator. The CST/EPC may communicate with only one CLS or eCLS at a time. The stimulator will not respond to any communication that does not come from a paired device. Additional mechanisms are in place to safeguard the integrity of the communication. There are no security settings that require input or control by the user.

17.4 Electromagnetic Interference

The following tables indicate the electromagnetic environment in which the Evoke SCS System is intended to operate. This is to ensure compliance with international standards for the electromagnetic interference (EMI) produced by the Evoke SCS System or the susceptibility of the Evoke SCS System to EMI. For more information on this section please contact a Saluda Representative.

⚠**Caution:** Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

17.4.1 Guidance and Manufacturer's Declarations

Table 17.8: Electromagnetic emissions.

The Evoke SCS System is intended for use in the electromagnetic environment specified below. The patient, doctor or any other user of the Evoke SCS System should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
Radiated disturbance, 30 MHz -6000 MHz CISPR 11 (EN 55011)	Group 1, Class B	Evoke SCS System is unlikely to produce electromagnetic interference with nearby electronic equipment.
Conducted Emissions 0.15 MHz -30 MHz CISPR 11 (EN 55011)	Class B	Evoke SCS System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable for the battery powered devices or device consuming less than 75 W from mains power outlet (Charger with power adapter)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable for the battery powered devices. Charger with power adapter complies with requirements of the standard	

Table 17.9: Electromagnetic immunity – electrostatic discharge and mains power.

The Evoke SCS System is intended for use in the electromagnetic environment specified below. The patient, doctor or any other user of the Evoke SCS System should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV gaseous discharge at 100 kHz repetition frequency	± 2 kV @100 kHz repetition frequency for power supply lines to Charger power adapter	Mains power quality should be that of a typical household, commercial or hospital environment. If the user of the Charger power adapter requires continued operation during mains power interruptions, it is recommended that the Charger power adapter be powered from an uninterruptible power supply or a battery.
Surge Immunity IEC 61000-4-5	± 0.5 kV, ± 1 kV	± 0.5 kV, ± 1 kV power supply line to Charger power adapter	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips: 0% residual voltage for 0.5 cycle at 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 °, 315 °; 0 % residual voltage; 1 cycle, and 70 % residual voltage; 25/30 cycles Single phase: at 0° Voltage Interruptions: 0% residual voltage; 250/300 cycles	Voltage Dips: 0% residual voltage for 0.5 cycle at 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 °, 315 °; 0% residual voltage for 1 cycle at 0 °; 70% residual voltage for 25 cycles at 0 °; Voltage Interruptions: 0% residual voltage for 250 cycles at 0 °; Interval between Events – min. 10s; Test cycle – 3 times;	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical household, commercial or hospital environment.

Table 17.10: Electromagnetic immunity – radio frequency.

The Evoke SCS System is intended for use in the electromagnetic environment specified below. The patient, doctor or any other user of the Evoke SCS System should ensure that it is used in such an environment.

⚠**Caution:** Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer to any part of the Evoke SCS System, including cables, than the recommended separation distance stated below (0.3 m, 12 inches). Otherwise, degradation of the performance of this equipment could result.

⚠**Caution:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz; 6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz 80% AM at 1 kHz	The Charger power adaptor functioned correctly during the test. Not applicable for the battery powered devices.	The separation distance between an interfering RF transmitter and any Evoke SCS should be greater than 0.3 m and the maximum power from the RF transmitter should not exceed 2 W or 28 V/m at a distance of 0.3 m.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m for professional healthcare facility environment or 10 V/m for home healthcare environment	
Proximity fields from RF wireless communications equipment	Up to 28 V/m at 0.3m at specified frequencies (refer Table 9, IEC 60601-1-2)	Tested at up to 28 V/m, devices continued to function during test.	

17.5 Federal Communications Commission (FCC)

17.5.1 Interference Statement for CLS, eCLS, CST, EPC

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

⚠FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The devices in the Evoke System may not interfere with stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

For MedRadio transmitters operating in the 401-406 MHz band, the following statement applies:

> This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter

has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

17.5.2 Charger

This device complies with Part 18 of the FCC Rules.

17.5.3 Radiation Exposure Statement

The products comply with the FCC portable RF exposure limit set forth for an uncontrolled environment and are safe for intended operation as described in this manual.

18 Glossary

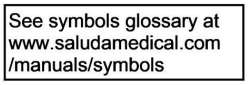
Table 18.1: Glossary.

Term	Definition
Accessory Belt	An elastic belt with a pouch to hold an eCLS or a Charger coil.
Charger	The device that charges the battery in the CLS.
Charger coil	A circular paddle connected to the Charger that is held over the CLS to charge the CLS battery.
Charger Power Adapter	The power supply adapter for the CLS Charger.
Clinical Interface (CI)	The computer loaded with the CPA used to program the CLS/eCLS.
Clinical System Transceiver (CST)	The device that connects to the CI via USB, and exchanges information between the CI and the CLS/eCLS.
Clinical Programming Application (CPA)	A computer program user interface that provides the functionalities required to program and analyze the performance of the CLS/eCLS.
Closed-Loop (CL) Stimulation	Stimulation that is automatically adjusted in response to a measured ECAP amplitude to maintain a target activation level. This is also known as ECAP-controlled closed-loop stimulation.
Closed-Loop Stimulator (CLS)	An implantable pulse generator capable of ECAP-controlled closed-loop stimulation.
Electrode	An electrical contact that may be employed to deliver therapeutic current or measure neural responses.
Evoke Patient Controller (EPC)	A remote control that allows the patient to adjust the therapy output from the CLS/eCLS.
Evoked Compound Action Potential (ECAP)	The measured sum of electrical signals from multiple nerve fibers elicited by an electrical stimulus.
External Closed-Loop Simulator (eCLS)	The eCLS is a non-implantable pulse generator capable of ECAP-controlled closed-loop stimulation.
Intraoperative Cable	Sterilized cable which enables the connection between leads/lead extensions and the eCLS in the operating room.
Lead	Insulated cable with a number of exposed electrodes at the distal end used in neurostimulation therapy.

Term	Definition
Lead Adapter	An adapter that enables the connection between leads/lead extensions and the eCLS during the trial stimulation period.
Lead Extension	Insulated cable that connects to the proximal end of a lead and in turn connects to either a CLS or lead adapter.
Open-Loop Stimulation	Stimulation delivered when closed-loop is disabled. The system delivers a fixed-output of stimulation current when closed-loop stimulation is disabled.
Paresthesia	Sensation felt by the patient as a result of activation of Aβ fibers by the stimulation pulses.
Spinal Cord Stimulation (SCS)	A treatment for chronic pain utilizing pulsed electrical signals delivered to the spinal cord.
Stimulation	The application of electrical current through electrodes.

19 Symbols

Table 19.1: Symbols.

Symbol	Definition
	Follow the instruction for use on this website: www.saludamedical.com/manuals
	Follow the instructions for use
	Follow the instructions for use at this website: www.saludamedical.com/manuals
	Symbols Glossary can be found on this website: www.saludamedical.com/manuals/symbols
	Catalogue number
	Serial number
	Lot number
 YYYY-MM-DD	Use by date (YYYY = year, MM = month, DD = day)

Symbol	Definition
	Caution
	Temperature limitation (°F and °C)
	Manufacturer
 YYYY-MM-DD	Date of manufacture (YYYY = year, MM = month, DD = day)
	Do not dispose of this product in the unsorted municipal waste stream – dispose of this product according to local regulations
	Type BF applied part
	Non-ionizing electromagnetic radiation
	Do not use if package is damaged
	MR Unsafe. Not safe to use with MR imaging.
	Contents
	Class II Medical Electrical Equipment
IP22	Ingress Protection Rating 22: • Protected against access of solid foreign objects greater than or equal to 12.5 mm diameter. • Protected against vertically dripping water when the device is tilted 15 degrees.
IP30	Ingress Protection Rating 30: • Protected against solid objects greater than or equal to 2.5 mm, and no protection against water.
IP54	Ingress Protection Rating 54: • Protected against failure from limited dust ingress. • Protected against failure from splashing water.

Symbol	Definition
	Sterilized using ethylene oxide
	Do not re-sterilize
	Do not re-use
	Single Sterile Barrier System
	Double Sterile Barrier System
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Peel open from here
	Telephone Number

20 Disposal of devices

Neither the CLS nor the eCLS should be disposed of in municipal waste facilities. Please return any items to Saluda Medical via your Saluda Medical representative for proper disposal. Surgical accessories should be disposed of in accordance with normal clinical practices.

21 Contact us

Most questions you have about programming the Evoke Closed-Loop Stimulator and Evoke External Closed-Loop Stimulator can be answered by reading this manual or looking at our website: http://www.saludamedical.com and/or http://www.saludamedical.com/manuals.

If you have any further questions, please contact your Saluda Medical representative. Alternatively, you can contact us via the details below, or email us at info@saludamedical.com.

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