Cleveland Clinic Innovations

Spinal Cord Buried Trial Removal Accessory

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PRODUCT

A device that easily removes a failed buried spinal cord stimulation trial without returning to the operating room

INDICATION

Neuro-stimulation, spinal cord stimulation, peripheral nerve stimulation

VALUE PROPOSITION

- This accessory eliminates the need for a second operation when a buried spinal cord stimulation trial fails
- Improved conversation rates for trial to permanent SCS
- Reduce patient risk and lead misplacement
- Fewer surgeries with better outcomes

DEVELOPMENT STAGE

Prototype developed

INTELLECTUAL PROPERTY

Patent Pending

PARTNERING OPPORTUNITY

Development and commercialization partnership

CONTACT INFORMATION

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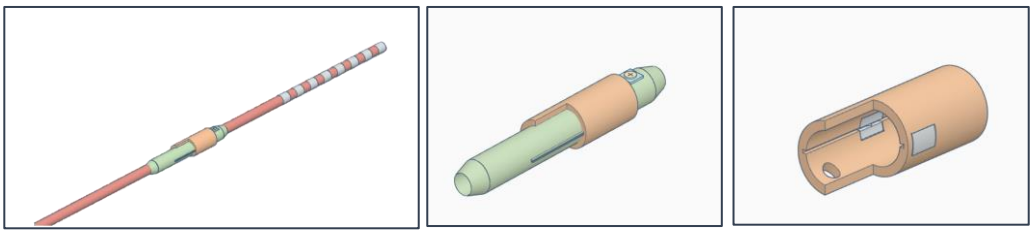
UNMET NEED

During spinal cord stimulation (SCS) therapy, one or two temporary trial electrode leads are traditionally inserted to determine response to neuromodulation. This reduces the chance that a costly medical device is not unnecessarily implanted into a non-responder. These temporary electrodes leads are percutaneously inserted into the epidural space and secured to the skin with suture. The electrode leads are connected to an external pulse generator for approximately one week to test the effect before removal in the office. If the effect is >50%, a permanent implant is inserted several weeks later. A permanent implant includes a pulse generator surgically placed beneath the skin that is connected to two new electrode leads implanted in the epidural space and anchored to the lumbodorsal fascia. Therefore, for most patients, the most critical part of the procedure that is both the most technically challenging and highest risk is performed twice for those who respond. An alternative method known as a “buried trial” involves inserting the electrode leads just once with anchors secured to the lumbodorsal fascia. An extension cable is then percutaneously inserted beneath the skin and connected to the lead proximal end. The extension cable is connected to the external pulse generator for the trial period. If the trial is successful, the patient returns to operating room to have the extension cable removed and the permanent pulse generator implanted. However, if the trial is not successful, the patient will still need to return to the operating room to have the skin incision opened and the electrode leads removed.

SOLUTION

This invention is an accessory that eliminates the need for the patient to return to the OR in the case of a failed ‘buried’ trial. The device simultaneously removes the anchors sutured to the fascia and both leads in the office. This device will increase the use of the buried trial option that better simulates the permanent implant and significantly reduce the patient risk. The invention includes an anchor placed over the permanent electrode and an accessory to release the suture surrounding the anchor if the buried trial is not successful.



Lead with anchor and anchor removal accessory. The removal accessory includes an embedded suture release mechanism activated through gentle traction in the office.

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