

Transcutaneous Spinal Cord Stimulation

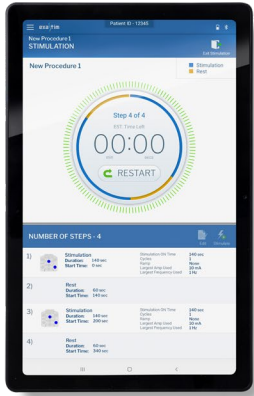
Issue Requiring a New Code

- No existing ICD-10-PCS code describes non-invasive spinal neuromodulation that activates spinal motor networks.
- Existing PCS codes apply only to implanted neurostimulators or peripheral electrical stimulation modalities.
- Accurate coding is needed to support data integrity, clinical tracking, and appropriate classification of this restorative neuromodulation therapy.

Clinical Context

- Approximately 300,000 individuals in the U.S. live with spinal cord injury (SCI).
- Current therapies focus on compensation rather than reactivation of spinal circuits.
- Functional electrical stimulation works peripherally and does not modulate spinal motor networks.
- Epidural stimulation is invasive, off-label for spinal cord injury, and accessible only at limited centers.
- No existing therapy provides non-invasive, spinal-segment-specific neuromodulation for voluntary motor re-engagement.

ExaStim® Technology Overview



Main System Components

- ExaStim® Portable Stimulator
- ReCure® Electrode Pad
- ReCure® Stimulation Cable
- ExaStim® Programmer
- ExaStim® Return Electrode Cable
- Return Electrodes

*image does not include return electrodes or return electrode cable



• ExaStim

- Non-invasive spinal neuromodulation system
- Delivers current-regulated stimulation to modulate spinal circuits involved in voluntary motor control.
- No implanted components, no incisions, and no imaging guidance required

• Multi-electrode array

- Sixteen independently programmable electrodes on a single pad allow selective spinal segment activation
- External electrodes placed over cervical or thoracolumbar spine; return electrodes on iliac crests

• Flexible stimulation settings

- Independent current control is designed to deliver highly customizable programming
- Enables activation of different muscle groups in individually or together

ExaStim® Transcutaneous Spinal Stimulation (TSS) Therapy



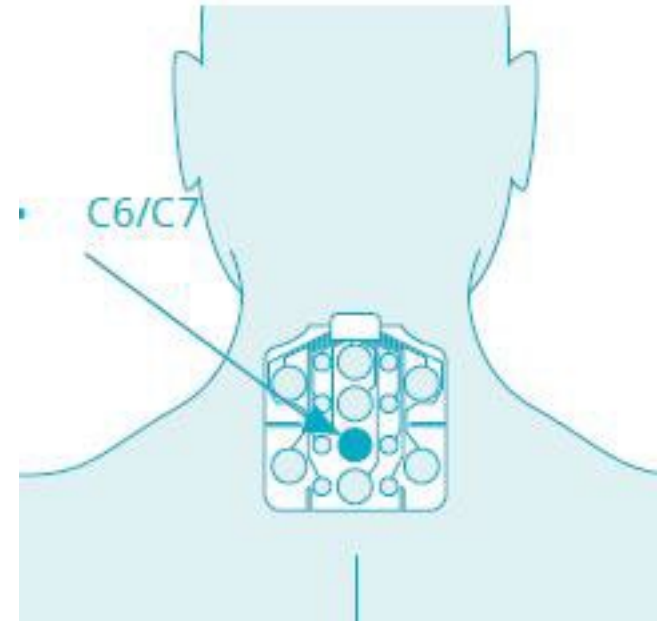
- Uses non-invasive electrical stimulation to re-engage the nervous system and re-active neural circuitries
- Delivers transcutaneous stimulation to the spinal cord and dorsal roots for activation of the central nervous system
- Engages spinal interneuronal circuits, facilitating voluntary movement and sensory processing
- Provides spatiotemporal targeting via a 16-channel multi-electrode array enabling activation of different muscle groups individually or together

ExaStim® is CE marked in Europe and FDA 510(k) cleared in the United States. It is not commercially available outside these markets..

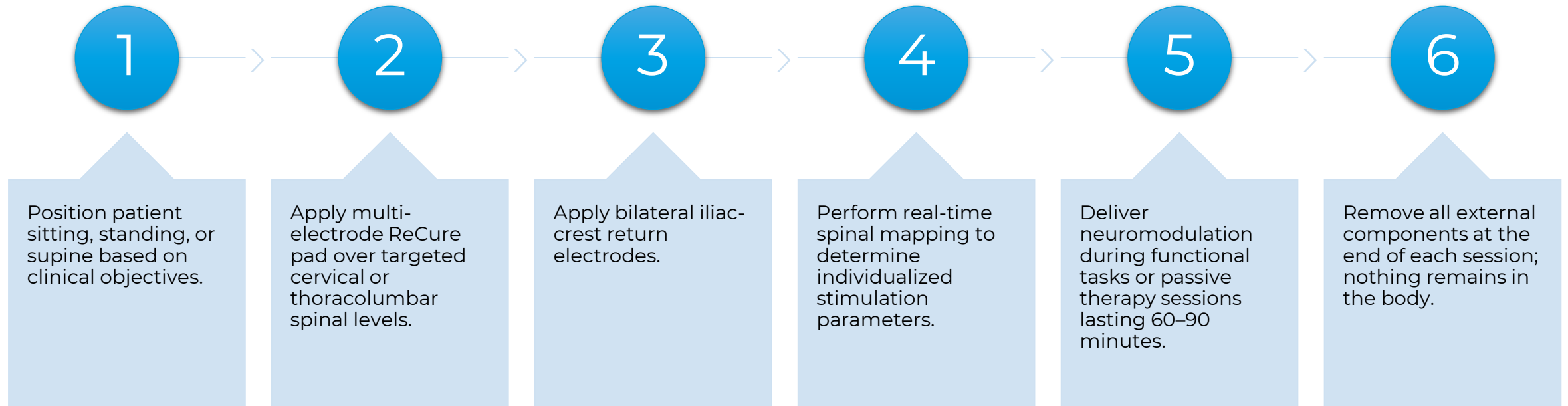
Indications for Use: The ANEUVO ExaStim® Stimulation System is indicated for the improvement of hand sensation and strength in individuals between 18 and 75 years old who present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury, when used in conjunction with functional task practice.

Anatomic Site Considerations

- Electrode array typically spans 2–3 vertebral levels.
- Placement may be cervical or thoracolumbar depending on motor objectives.
- Functional target is the spinal cord and associated motor circuits, not peripheral musculature.
- Mapping is an integral therapeutic step, not preparatory or diagnostic.



Key Procedural Steps



Nature of the Device (Not Permanent)

Entire ExaStim system remains external to the body.

No implanted electrodes, leads, or generators are used.

No removal or revision codes are applicable.

ReCure electrode pads are single-use; return electrodes are reusable for the same patient.

ASPIRE™ Study Key Results

A multi-center, double-blinded RCT of 128 patients with chronic, traumatic SCI

- Patients receiving ExaStim
 - Saw **meaningful strength improvements** within 8 weeks of therapy that were sustained even after therapy ended
 - Demonstrated **2x greater functional improvement** than those who did not receive ExaStim
 - **85%** experienced an **improvement in dexterity** of one or both hands that was sustained even after therapy ended
 - Showed a **measurable increase in light touch sensation** of the hand

Regulatory and Clinical Readiness

- FDA 510(k) Clearance in March 2026
- Evidence from ASPIRE™ Study and ASPIRE™ Home Study
 - ASPIRE (n=128): Multi-center, sham-controlled, double-blinded RCT
 - ASPIRE Home Study (n=30): Single-arm prospective observational study for home use
- CE Mark Approval in April 2025
- Single-center pilot studies completed for pediatric cerebral palsy and adult lower limb SCI

Distinction From Existing Procedures

- Not peripheral electrical stimulation or TENS/FES modalities.
- Not implanted or percutaneous spinal cord stimulation.
- Not diagnostic imaging or guidance.
- Unique attributes: targeted spinal circuit activation, multi-channel mapping, restorative intent, non-invasive application.
- No PCS code describes a non-invasive spinal neuromodulation procedure for voluntary motor restoration.

Medical Record Documentation

- Part of the rehabilitation or therapy session
- Typically appears in the daily therapy progress note, neuromodulation treatment log, or physician order record.
- The clinician records electrode placement location (cervical or thoracolumbar), stimulation parameters (amplitude, frequency, pulse width), session duration, patient response, and any observed motor outcomes.
- Session data automatically captured by the ExaStim software may be exported or integrated into the electronic medical record to support continuity of care, treatment tracking, and billing documentation. The note should convey the use of a non-invasive, circuit-level spinal neuromodulation procedure performed as part of a rehabilitation plan.

Naming Conventions

- ExaStim System
- Non-Invasive spinal neuromodulation for motor network activation
- Transcutaneous spinal stimulation
- Spinal network modulation
- Spinal motor re-engagement therapy

Summary and Request

- Request approval for new ICD-10-PCS code for April 1, 2027 implementation.

Thank You

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