PACIFIC NEUROSCIENCE INSTITUTE℠

JOHN WAYNE CANCER INSTITUTE
at Providence Saint John's Health Center

CLINICAL TRIAL ANNOUNCEMENT

Peripheral Nerve Stimulation with StimRouter™ Neuromodulation System for Post-Stroke Shoulder Pain

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Official Title: StimRouter™ Neuromodulation System: Implanted peripheral nerve stimulation for pain management when treating patients with chronic post-stroke shoulder-pain

Post-stroke shoulder pain (PSSP) is a common result of stroke, affecting 30-70% of individuals. PSSP is increased with arm movement, thus making rehabilitation more difficult and drastically interferes with activities of daily living resulting in poor quality of life. Current standard lines of clinical treatment for PSSP include compensatory techniques and symptom management, such as taping, slinging, and pain management, which are options to have shown only marginal benefits. An estimated 20-30% of stroke survivors still have shoulder pain 4 years post stroke.

The StimRouter™ has been FDA approved in adults with chronic pain of peripheral nerve origin and has shown a significant decrease in pain with no severe adverse events related to the device. Based on the additional potential benefits associated with alleviating PSSP, as evidenced by the literature, the current study is aimed at collecting additional data on the StimRouter therapy in individuals with post-stroke shoulder pain.

Key Inclusion Criteria:

- Age ≥ 18years
- Minimum 3 months of severe chronic focal post-stroke shoulder pain of axillary nerve origin
- Stable regimen of pain medications for ≥ 4 weeks prior to implant

Key Exclusion Criteria:

- H/o shoulder pathology (e.g. rotator cuff tear, frozen shoulder, etc.) at target limb
- Diagnosed/confirmed shoulder dysfunction
- Any metallic implant in the immediate area intended for implant
- Have demand-type cardiac pacemaker, defibrillator, or electrical nerve implant